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GOVERNMENT OF INDIA

स्वास्थ्य एवं परिवार कल्याण मंत्रालय
MINISTRY OF HEALTH AND FAMILY WELFARE

स्वास्थ्य विभाग
(Department of Health)

औषधि और प्रसाधन सामग्री अधिनियम एवं नियमावली
THE DRUGS AND COSMETICS ACT AND RULES

औषधि और प्रसाधन सामग्री अधिनियम, 1940

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यथासंशोधित

THE DRUGS AND COSMETICS ACT, 1940

as amended by the Drugs (Amendment) Act, 1955, the Drugs (Amendment), Act, 1960, the Drugs (Amendment) Act, 1962, the Drugs and Cosmetics (Amendment) Act, 1964, and the Drugs and Cosmetics (Amendment) Act, 1972.

और उसके अन्तर्गत बनाई गई

औषधि और प्रसाधन सामग्री नियमावली, 1945

AND

THE DRUGS AND COSMETICS RULES, 1945

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as corrected up to the 1st May, 1979

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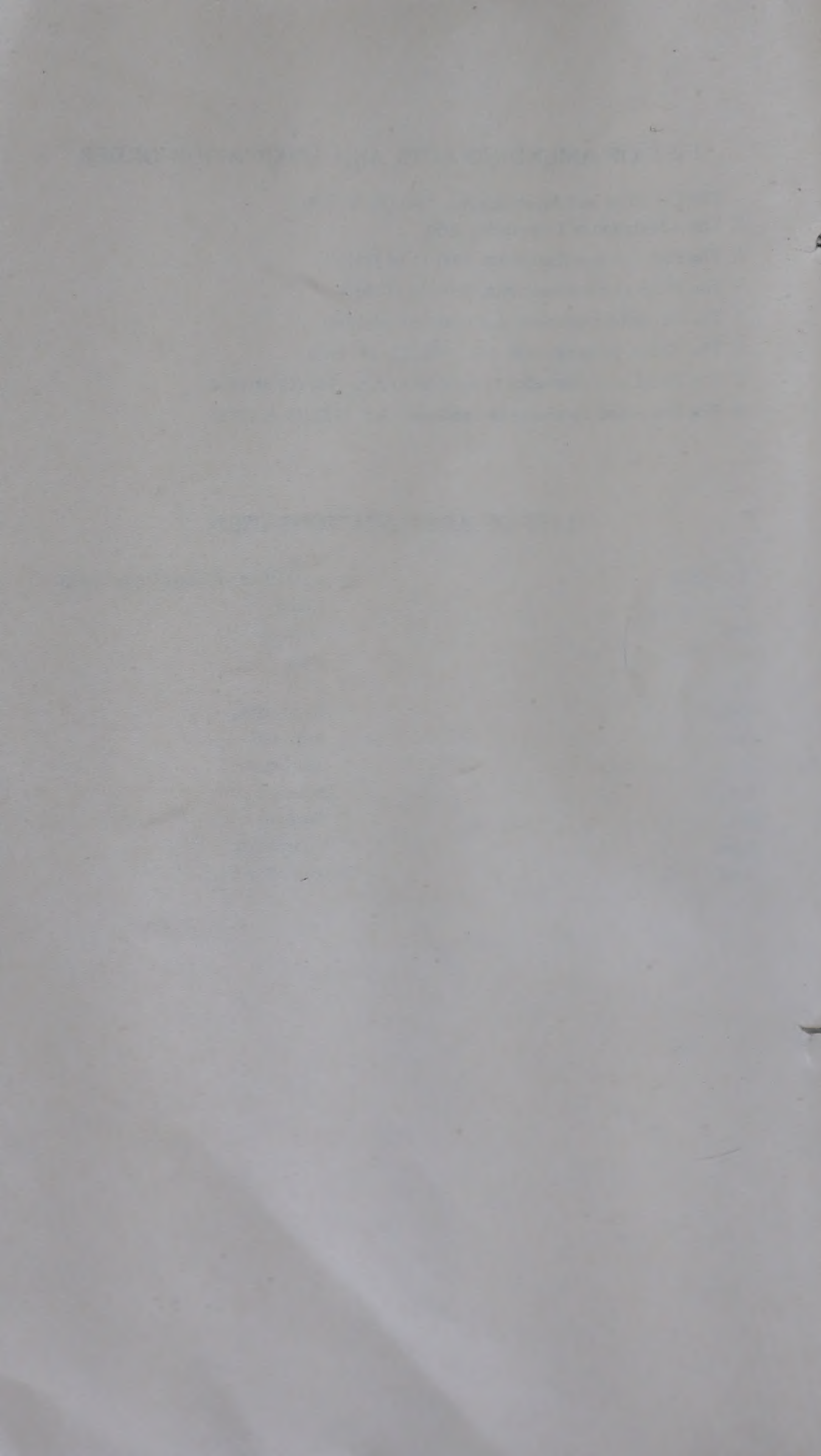
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LIST OF ABBREVIATIONS USED

A.O. 1950	for Adaptation of Laws Order, 1950.
Cl.	" Clause.
Ins.	" Inserted.
P.	" Page.
Pt.	" Part.
Reg.	" Regulation.
Rep.	Repealed.
S.	" Section.
Sch.	" Schedule.
Sec.	" Section.
Subs.	" Substituted.
w.e.f.	" with effect from.



THE DRUGS AND COSMETICS ACT, 1940

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THE DRUGS AND COSMETICS ACT, 1940

23 OF 1940¹

[10th April, 1940]

[PASSED BY THE INDIAN LEGISLATURE]

(Received the assent of the Governor General on the 10th April, 1940)

As Amended by Act No. II of 1955

[PASSED BY THE INDIAN PARLIAMENT]

(Received the assent of the President on the 15th April, 1955)

As Amended by Act No. 35 of 1960

[PASSED BY THE INDIAN PARLIAMENT]

(Received the assent of the President on the 15th September, 1960)

As Amended by Act No. 21 of 1962

[PASSED BY THE INDIAN PARLIAMENT]

(Received the assent of the President on the 27th June, 1962)

As Amended by Act No. 13 of 1964

[PASSED BY THE INDIAN PARLIAMENT]

(Received the assent of the President on the 12th May, 1964)

As Amended by Act No. 19 of 1972

[PASSED BY THE INDIAN PARLIAMENT]

(Received the assent of the President on the 31st May, 1972)

An Act to regulate the import, manufacture, distribution and sale of drugs ²[and cosmetics].

WHEREAS it is expedient to regulate the ³[import, manufacture, distribution and sale] of drugs ²[and cosmetics];

AND WHEREAS the Legislatures of all the Provinces have passed resolutions in terms of section 103 of the Government of India Act, 1935 26 Geo. 5, c. 2, in relation to such of the above-mentioned matters and matters ancillary thereto as are enumerated in List II of the Seventh Schedule to the said Act;

¹For Statement of Objects and Reasons, see Gazette of India, 1940, Pt. V, p. 34; for the Report of the Select Committee, see *ibid.*, p. 143.

The Act has been applied to all the partially excluded areas in the State of Orissa, see Orissa Government Notification No. 3358-LSG., dated the 25th August, 1941.

²Ins. by Act 21 of 1962, s. 2 (w.e.f. 27-7-1964).

³Subs. by the A. O. 1950 for certain words.

It is hereby enacted as follows :—

CHAPTER I

INTRODUCTORY

1. *Short title, extent and commencement.*—(1) This Act may be called the Drugs ¹[and Cosmetics] Act, 1940.

(2) It extends to the whole of India² * * *

(3) It shall come into force at once; but Chapter III shall take effect only from such ³date as the Central Government may, by notification in the Official Gazette, appoint in this behalf, and Chapter IV shall take effect in a particular State only from such ³date as the State Government may, by like notification, appoint in this behalf :

⁴[Provided that in relation to the State of Jammu and Kashmir, Chapter III shall take effect only from such date after the commencement of the Drugs and Cosmetics (Amendment) Act, 1972 19 of 1972, as the Central Government may, by notification in the Official Gazette, appoint in this behalf.]

2. *Application of other laws not barred.*—The provisions of this Act shall be in addition to and not in derogation of, the Dangerous Drugs Act, 1930 2 of 1930, and any other law for the time being in force.

3. *Definitions.*—In this Act, unless there is anything repugnant in the subject or context,—

⁵[(a) “*Avurvedic (including Siddha) or Unani drug*” includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings, mentioned in, and processed and manufactured exclusively in accordance

¹Ins. by Act 21 of 1962, s. 3 (w.e.f. 27-7-1964).

²The words “except the State of Jammu & Kashmir” omitted by Act 19 of 1972, s. 2.

³1st April, 1947; see Notification No. F. 28 (10) (3) 45-H (I), dated the 2nd September, 1946, Gazette of India, 1946, Pt. I, p. 1349.

Chapter IV came into force in the States of Delhi, Ajmer and Coorg on the 1st April, 1947, see *ibid.*, Chapters III and IV came into force in the States of Himachal Pradesh, Bilaspur, Kutch, Bhopal, Tripura, Vindhya Pradesh and Manipur on the 1st April, 1953, *vide* Notification No. S.R.O. 663, dated the 30th March, 1953, Gazette of India, Pt. II, Sec. 3, p. 451.

Chapter IV came into force in the Union territory of Dadra and Nagar Haveli w.e.f. 1st August, 1968, see Notification No. ADM/Law/117(74) dated the 20th July, 1968, Gazette of India, Pt. III, Sec. 3, p. 128.

The Act is extended to Dadra and Nagar Haveli by Reg. 6 of 1963, s.2 and Sch. I; to Pondicherry by Reg. 7 of 1963, s. 3 and Sch. I; to Goa, Daman and Diu, by Reg. 11 of 1963, s. 3 and Sch. and to Laccadive, Minicoy and Amindivi Islands by Reg. 8 of 1965, s. 3 and Sch.

⁴Added by Act 19 of 1972, s. 2.

⁵Ins. by Act 13 of 1964, s. 2 (w.e.f. 15-9-1964).

with the formulae described in, the authoritative books of Ayurvedic (including Siddha) and Unani (Tibb) systems of medicine, specified in the First Schedule;]

¹[(aa) "the Board" means—

(i) in relation to Ayurvedic (including Siddha) or Unani drug, the Ayurvedic and Unani Drugs Technical Advisory Board constituted under section 33C; and

(ii) in relation to any other drug or cosmetic, the Drugs Technical Advisory Board constituted under section 5;]

²[³(aaa)] "cosmetic" means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic, but does not include soap;]

⁴[(b) "drug" includes—

(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or ⁵[in the diagnosis, treatment], mitigation or prevention of disease in human beings or animals ^{1***}; and

(ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of ⁷[vermin] or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;]

⁸[(c) "Government Analyst" means—

(i) in relation to Ayurvedic (including Siddha) or Unani drug, a Government Analyst appointed by the Central Government or a State Government under section 33F; and

(ii) in relation to any other drug or cosmetic, a Government Analyst appointed by the Central Government or a State Government under section 20;]

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¹Original cl. (a) was relettered as cl. (aa) and subs. by s. 2, *ibid.* (w.e.f. 15-9-1964).

²Ins. as cl. (aa) by Act 21 of 1962, s. 4 (w.e.f. 27-7-1964).

³Relettered by Act 13 of 1964, s. 2 (w.e.f. 15-9-1964).

⁴Subs. by Act 11 of 1955, s. 2, for cl. (b).

⁵Subs. by Act 35 of 1960, s. 2, for "in the treatment" (w.e.f. 16-3-1961).

⁶Certain words omitted by Act 13 of 1964, s. 2 (w.e.f. 15-9-1964).

⁷Subs. by s. 2, *ibid.*, for "vermins" (w.e.f. 15-9-1964).

⁸Subs. by s. 2, *ibid.*, for cl. (c) (w.e.f. 15-9-1964).

⁹Cl. (d) omitted by Act 19 of 1972, s. 3.

¹[(e) "Inspector" means—

(i) in relation to Ayurvedic (including Siddha) or Unani drug, an Inspector appointed by the Central Government or a State Government under section 33G; and

(ii) in relation to any other drug or cosmetic, an Inspector appointed by the Central Government or a State Government under section 21;]

²[³(f)] "manufacture" in relation to any drug ⁴[or cosmetic] includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug ⁴[or cosmetic] with a view to its sale and distribution but does not include the compounding or dispensing ⁵[of any drug, or the packing of any drug or cosmetic,] in the ordinary course of retail business; and "to manufacture" shall be construed accordingly;]

⁶[(g)] "to import", with its grammatical variations and cognate expressions means to bring into ⁷[India];

⁸[⁶(h)] "patent or proprietary medicine" means a drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being or any other pharmacopoeia authorised in this behalf by the Central Government after consultation with the Board;]

⁹[⁶(i)] "prescribed" means prescribed by rules made under this Act.]

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¹¹3A. *Construction of references to any law not in force or any functionary not in existence in the State of Jammu and Kashmir.*—Any reference in this Act to any law which is not in force, or any functionary not in existence, in the State of Jammu and Kashmir, shall, in relation to that State, be construed as a reference to the corresponding law in force, or to the corresponding functionary in existence, in that State.]

¹Subs. by Act 13 of 1964, s. 2, for cl. (e) (w.e.f. 15-9-1964).

²Cl. (bbb) ins. by Act 11 of 1955, s. 2.

³Cl. (bbb) relettered as cl. (f) by Act 35 of 1960, s. 2 (w.e.f. 16-3-1961).

⁴Ins. by Act 21 of 1962, s. 4 (w.e.f. 27-7-1964).

⁵Subs. by s. 4, *ibid.*, for "or the packing of any drug".

⁶Cls. (c), (d) and (e) relettered as cls. (g), (h) and (i) respectively by Act 35 of 1960, s. 2 (w.e.f. 16-3-1961).

⁷Subs. by Act 3 of 1951, s. 3 and Sch., for "the States".

⁸Subs. by Act 13 of 1964, s. 2, for cl. (h), (w.e.f. 15-9-1964).

⁹Subs. by Act 11 of 1955, s. 2, for original cl. (e).

¹⁰Cl. (f), ins. by the A. O. 1950, omitted by Act 3 of 1951, s. 3 and Sch.

¹¹Ins. by Act 19 of 1972, s.4.

4. *Presumption as to poisonous substances.*—Any substance specified as poisonous by rule made under Chapter III or Chapter IV ¹[or Chapter IVA] shall be deemed to be a poisonous substance for the purposes of Chapter III or Chapter IV ¹[or Chapter IVA], as the case may be.

(Chapter II.—*The Drugs Technical Advisory Board, the Central Drugs Laboratory and the Drugs Consultative Committee.*)

CHAPTER II

THE DRUGS TECHNICAL ADVISORY BOARD, THE CENTRAL DRUGS LABORATORY AND THE DRUGS CONSULTATIVE COMMITTEE

5. *The Drugs Technical Advisory Board.*—(1) The Central Government shall, as soon as may be, constitute a Board (to be called the Drugs Technical Advisory Board) to advise the Central Government and the State Governments on technical matters arising out of the administration of this Act and to carry out the other functions assigned to it by this Act.

²[(2) The Board shall consist of the following members, namely :—

(i) the Director General of Health Services, *ex officio*, who shall be Chairman;

(ii) the Drugs Controller, India, *ex officio*;

(iii) the Director of the Central Drugs Laboratory, Calcutta, *ex officio*;

(iv) the Director of the Central Research Institute, Kasauli, *ex officio*;

(v) the Director of the Indian Veterinary Research Institute, Izatnagar, *ex officio*;

(vi) the President of the Medical Council of India, *ex officio*;

(vii) the President of the Pharmacy Council of India, *ex officio*;

(viii) the Director of the Central Drug Research Institute, Lucknow, *ex officio*;

(ix) two persons to be nominated by the Central Government from among persons who are in charge of drugs control in the States;

(x) one person, to be elected by the Executive Committee of the Pharmacy Council of India, from among teachers in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of an Indian University or a college affiliated thereto;

(xi) one person, to be elected by the Executive Committee of the Medical Council of India, from among teachers in medicine or therapeutics on the staff of an Indian university or a college affiliated thereto;

(xii) one person to be nominated by the Central Government from the pharmaceutical industry;

(xiii) one pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research;

¹Ins. by Act 13 of 1964, s. 3 (w.e.f. 15-9-1964).

²Subs. by Act 13 of 1964, s. 4, for sub-section (2) w.e.f. 15-9-1964).

(xiv) one person to be elected by the Central Council of the Indian Medical Association;

(xv) one person to be elected by the Council of the Indian Pharmaceutical Association;

(xvi) two persons holding the appointment of Government Analyst under this Act, to be nominated by the Central Government.]

(3) The nominated and elected members of the Board shall hold office for three years, but shall be eligible for re-nomination and re-election :

¹[Provided that the person nominated or elected, as the case may be, under clause (ix) or clause (x) or clause (xi) or clause (xvi) of sub-section (2) shall hold office for, so long as he holds the appointment of the office by virtue of which he was nominated or elected to the Board.]

(4) The Board may, subject to the previous approval of the Central Government, make bye-laws fixing a quorum and regulating its own procedure and the conduct of all business to be transacted by it.

(5) The Board may constitute sub-committees and may appoint to such sub-committees for such periods, not exceeding three years, as it may decide, or temporarily for the consideration of particular matters, persons who are not members of the Board.

(6) The functions of the Board may be exercised notwithstanding any vacancy therein.

(7) The Central Government shall appoint a person to be Secretary of the Board and shall provide the Board with such clerical and other staff as the Central Government considers necessary.

6. *The Central Drugs Laboratory.*—(1) The Central Government shall, as soon as may be, established a Central Drugs Laboratory under the control of a Director to be appointed by the Central Government, to carry out the functions entrusted to it by this Act or any rules made under this Chapter :

Provided that, if the Central Government so prescribes, the functions of the Central Drugs Laboratory in respect of any drug or class of drugs ²[or cosmetic or class of cosmetics] shall be carried out at the Central Research Institute, Kasauli, or at any other prescribed Laboratory and the functions of the Director of the Central Drugs Laboratory in respect of such drug or class of drugs ²[or such cosmetic or class of cosmetics] shall be exercised by the Director of that Institute or of that other Laboratory, as the case may be.

(2) the Central Government may, after consultation with the Board, make rules prescribing—

(a) the functions of the Central Drugs Laboratory;

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¹Subs. by s. 4, *ibid*, for the proviso (w.e.f. 15-9-1964).

²Ins. by Act 21 of 1962, s. 5 (w.e.f. 27-7-1964).

³Cls. (b) and (c) omitted by Act 11 of 1955, s. 4.

(d) the procedure for the submission to the said Laboratory ¹[under Chapter IV or Chapter IVA] of samples of drugs ²[or cosmetics] for analysis or test, the forms of the Laboratory's reports thereon and the fees payable in respect of such reports;

(e) such other matters as may be necessary or expedient to enable the said Laboratory to carry out its functions;

(f) the matters necessary to be prescribed for the purposes of the proviso to sub-section (1).

7. *The Drugs Consultative Committee.*—(1) The Central Government may constitute an advisory committee to be called "the Drugs Consultative Committee" to advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any matter tending to secure uniformity throughout ³[India] in the administration of this Act.

(2) The Drugs Consultative Committee shall consist of two representatives of the Central Government to be nominated by that Government and one representative of each State Government to be nominated by the State Government concerned.

(3) The Drugs Consultative Committee shall meet when required to do so by the Central Government and shall have power to regulate its own procedure.

⁴[7A. Sections 5 and 7 not apply to Ayurvedic (including Siddha) or Unani drugs.—Nothing contained in sections 5 and 7 shall apply to Ayurvedic (including Siddha) or Unani drugs.]

CHAPTER III

IMPORT OF DRUGS

8. *[Standards of quality.]*—(1) For the purposes of this Chapter, the expression "standard quality" means—

(a) in relation to a drug, that the drug complies with the standard set out in ⁵[the Second Schedule], and

(b) in relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed.]

(2) The Central Government, after consultation with the Board and after giving by notification in the Official Gazette not less than three months' notice of its intention so to do, may by a like notification add to or otherwise amend ⁶[the Second Schedule], for the purpose of this Chapter, and thereupon ⁶[the Second Schedule] shall be deemed to be amended accordingly.

¹Subs. by Act 13 of 1964, s. 5, for "under Chapter IV" (w.e.f. 15-9-1964).

²Ins. by Act 21 of 1962, s. 5 (w.e.f. 27-7-1964)

³Subs. by Act 3 of 1951, s. 3 and Sch., or "the States".

⁴Ins. by Act 13 of 1964, s. 6 (w.e.f. 15-9-1964).

⁵Subs. by Act 21 of 1962, s. 6, for sub-section (1) (w.e.f. 27-7-1964).

⁶Subs. by Act 13 of 1964, s. 7, for "the Schedule" (w.e.f. 15-9-1964).

9. *Misbranded drugs.*—For the purposes of this Chapter a drug shall be deemed to be misbranded—

(a) if it is an imitation of, or substitute for, or resembles in a manner likely to deceive, another drug, or bears upon it or upon its label or container the name of another drug, unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

(b) if it purports to be the product of a place or country of which it is not truly a product; or

(c) if it is imported under a name which belongs to another drug; or

(d) if it is so coloured, coated, powdered or polished that damage is concealed, or if it is made to appear of better or greater therapeutic value than it really is; or

(e) if it is not labelled in the prescribed manner; or

(f) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular; or

(g) if the label or container bears the name of an individual or company purporting to be the manufacturer or producer of the drug, which individual or company is fictitious or does not exist.

9A. *Misbranded cosmetics.*—For the purposes of this Chapter, a cosmetic shall be deemed to be misbranded—

(a) if it is an imitation of, or a substitute for, or resembles in a manner likely to deceive, another cosmetic; or

(b) if it purports to be the product of a place or country of which it is not truly a product; or

(c) if it contains a colour which is not prescribed; or

(d) if it is imported under a name which belongs to another cosmetic; or

(e) if it is not labelled in the prescribed manner; or

(f) if its label or container bears the name of an individual or company purporting to be the manufacturer or producer of the cosmetic which individual or company is fictitious or does not exist; or

(g) if the label or container bears any statement which is false or misleading in any particular.]

19B. ~~Adulterated drugs.~~—For the purposes of this Chapter, a drug shall be deemed to be adulterated—

(a) if it consists, in whole or in part, of any filthy, putrid or decomposed substance; or

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) if any substance has been—

(i) mixed or packed therewith so as to reduce its quality or strength; or

(ii) substituted wholly or in part therefor.

Explanation.—For the purpose of clause (a), a drug shall not be deemed to consist, in whole or in part, of any decomposed substance only by reason of the fact that such decomposed substance is the result of any natural decomposition of the drug within the period, if any, specified on the label of the drug within which the drug is to be used.

Provided that such decomposition is not due to any negligence on the part of the manufacturer of the drug or the importer or the dealer thereof and that it does not render the drug injurious to health.]

10. *Prohibition of import of certain drugs or cosmetics.*—From such date as may be fixed by the Central Government by notification in the Official Gazette in this behalf, no person shall import—

(a) any drug³ [or cosmetic] which is not of standard quality;

(b) any misbranded drug or misbranded cosmetic;

(bb) any adulterated drug;

(c) any drug³ [for cosmetic] for the import of which a licence is prescribed, otherwise than under and in accordance with such licence;

¹Ins. by Act 13 of 1964, s. 8 (w.e.f. 15-9-1964).

²1st April, 1947 for cls. (a), (b), (c), (e) and (f), and 1st April, 1949 for cl. (d) see Notification No. 18-12/46-D.I., dated the 11th February, 1947, Gazette of India, 1947, Pt. 1, P. 189 as amended by Notification No. F. I-2/48-D(I), dated the 29th September, 1948.

³1st April, 1953 for the States of Himachal Pradesh, Bilaspur, Kutch, Bhopal, Tripura, Vindhya Pradesh and Manipur; vide Notification No. S.R.O. 666, dated the 30th March, 1953, Gazette of India, 1953, Pt. II, Sec. 3, p. 451.

³Ins. by Act 21 of 1962, s. 8 (w.e.f. 27-7-1964).

⁴Subs. by s. 8, *ibid.*, for cl. (b) (w.e.f. 27-7-1964).

⁵Ins. by Act 13 of 1964, s. 9 (w.e.f. 15-9-1964).

¹[(d) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of ingredients contained in it, in a manner readily intelligible to the members of the medical profession;]

(e) any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect, as may be prescribed;

²[(ee) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;]

(f) any drug ³[or cosmetic] the import of which is prohibited by rule made under this Chapter :

Provided that nothing in this section shall apply to the import, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis or for personal use :

Provided further that the Central Government may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the import of any drug or class of drugs not being of standard quality.

Explanation.—The formula or list of ingredients mentioned in clause (d) shall be deemed to be true and a sufficient compliance with that sub-clause if, without disclosing a full and detailed recipe of the ingredients, it indicates correctly all potent or poisonous substances contained therein together with an approximate statement of the composition of the medicine.

11. *Application of law relating to sea customs and powers of Customs Officers.*—(1) The law for the time being in force relating to sea customs and to goods, the import of which is prohibited by section 18 of the Sea Customs Act, 1878³ (8 of 1878) shall, subject to the provisions of section 13 of this Act, apply in respect of drugs ⁴[and cosmetics] the import of which is prohibited under this Chapter, and officers of Customs and officers empowered under that Act to perform the duties imposed thereby on a Customs Collector and other officers of Customs, shall have the same powers in respect of such drugs ⁴[and cosmetics] as they have for the time being in respect of such goods as aforesaid.

⁵[(2) Without prejudice to the provisions of sub-section (1), the Customs Collector or any officer of the Government authorized by the Central Government in this behalf, may detain any imported package which he suspects to contain any drug ⁴[or cosmetic] the import of which is prohibited

¹Subs. by Act 11 of 1955, s. 5, for cl. (d).

²Ins. by Act 21 of 1962, s. 8 (w.e.f. 27-7-1964).

³Now see the Customs Act, 1962.

⁴Ins. by Act 21 of 1962, s. 9 (w.e.f. 27-7-1964).

⁵Subs. by Act 11 of 1955, s. 6, for sub-section (2).

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under this Chapter and shall forthwith report such detention to the Drugs Controller, India, and, if necessary, forward the package or sample of any suspected drug¹ [or cosmetic] found therein to the Central Drugs Laboratory.]

12. *Power of Central Government to make rules.*—(1) The Central Government may, after consultation with the Board and after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter :

²[Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.]

(2) Without prejudice to the generality of the foregoing power, such rules may—

(a) specify the drugs or classes of drugs³ [or cosmetics or classes of cosmetics] for the import of which a licence is required, and prescribe the form and conditions of such licences, the authority empowered to issue the same, and the fees payable therefor ;

(b) prescribe the methods of test or analysis to be employed in determining whether a drug⁴ [or cosmetic] is of standard quality;

(c) prescribe, in respect of biological and organometallic compounds, the units or methods of standardisation;

⁴[(cc) prescribe under clause (d) of section 9B the colour or colours which a drug may bear or contain for purposes of colouring;]

(d) specify the diseases or ailments which an imported drug may not purport or claim⁵ [to prevent, cure or mitigate] and such other effects which such drug may not purport or claim to have;

(e) prescribe the conditions subject to which small quantities of drugs, the import of which is otherwise prohibited under this Chapter, may be imported for the purpose of examination, test or analysis or for personal use ;

(f) prescribe the places at which drugs³ [or cosmetics] may be imported, and prohibit their import at any other place;

(g) require the date of manufacture and the date of expiry of potency to be clearly and truly stated on the label or container of any

¹Ins. by Act 21 of 1962 s. 9 (w.e.f. 27-7-1964)

²Ins. by Act 11 of 1955, s. 7 (w.e.f. 27-7-1955)

³Ins. by Act 21 of 1962, s. 10 (w.e.f. 27-7-1964).

⁴Ins. by Act 13 of 1964, s. 10 (w.e.f. 15-9-1964).

⁵Subs. by Act 11 of 1955, s. 7, for "to cure or mitigate".

specified imported drug or class of such drugs, and prohibit the import of the said drug or class of drugs after the expiry of a specified period from the date of manufacture;

(h) regulate the submission by importers, and the securing of samples of drugs [or cosmetics] for examination, test or analysis by the Central Drugs Laboratory, and prescribe the fees, if any, payable for such examination, test or analysis;

(i) prescribe the evidence to be supplied, whether by accompanying documents or otherwise, of the quality of drugs [or cosmetics] sought to be imported, the procedure of officers of Customs in dealing with such evidence, and the manner of storage at places of import of drugs [or cosmetics] detained pending admission;

(j) provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter and the rules made thereunder of drugs [or cosmetics] imported for the purpose only of transport through, and export from, ²[India];

(k) prescribe the conditions to be observed in the packing in bottles, packages or other containers, of imported drugs [or cosmetics];

(l) regulate the mode of labelling drugs [or cosmetics] imported for sale in packages, and prescribe the matters which shall or shall not be included in such labels;

(m) prescribe the maximum proportion of any poisonous substance which may be added to or contained in any imported drug, prohibit the import of any drug in which that proportion is exceeded, and specify substances which shall be deemed to be poisonous for the purposes of this Chapter and the rules made thereunder;

(n) require that the accepted scientific name of any specified drug shall be displayed in the prescribed manner on the label or wrapper of any imported patent or proprietary medicine containing such drug;

(o) provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter or the rules made thereunder of any specified drug or class of drugs [or cosmetic or class of cosmetics].

13. Offences. (1) Whoever contravenes any of the provisions of this Chapter or of any rule made thereunder shall in addition to any penalty to which he may be liable under the provision of section 14 be punishable with imprisonment which may extend to one year, or with fine which may extend to five hundred rupees, or with both.

(2) Whoever, having been convicted under sub-section (1), is again convicted under that sub-section shall in addition to any penalty as aforesaid, be punishable with imprisonment which may extend to two years, or with fine which may extend to one thousand rupees, or with both.

¹Ins. by Act 21 of 1962, s. 10 (w.e.f. 27-7-1964).

²Subs. by Act 3 of 1951, s. 3 and Sch. for "the States".

14. *Confiscation*.—Where any offence punishable under section 13 has been committed, the consignment of the drugs ¹[or cosmetics] in respect of which the offence has been committed shall be liable to confiscation.

15. *Jurisdiction*.—No Court inferior to that of a Presidency Magistrate or of a Magistrate of the first class shall try an offence punishable under section 13.

CHAPTER IV

MANUFACTURE, SALE AND DISTRIBUTION OF DRUGS

16. *Standards of quality*.—²[(1) For the purposes of this Chapter, the expression “standard quality” means—

(a) in relation to a drug, that the drug complies with the standard set out in ³[the Second Schedule], and

(b) in relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed.]

(2) The ⁴[Central Government], after consultation with the Board and after giving by notification in the Official Gazette not less than three months' notice of its intention so to do, may by a like notification add to or otherwise amend ³[the Second Schedule] for the purposes of this Chapter, and thereupon ³[the Second Schedule] shall be deemed to be amended accordingly.

17. *Misbranded drugs*.—For the purposes of this Chapter a drug shall be deemed to be misbranded—

(a) if it is an imitation of, or substitute for, or resembles in a manner likely to deceive, another drug, or bears upon it or upon its label or container the name of another drug, unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

(b) if it purports to be the product of a place or country of which it is not truly a product; or

(c) if it is sold, or offered or exposed for sale, under a name which belongs to another drug; or

(d) if it is so coloured, coated, powdered or polished that damage is concealed, or if it is made to appear of better or greater therapeutic value than it really is; or

(e) if it is not labelled in the prescribed manner; or

¹Ins. by Act 21 of 1962, s. 11 (w.e.f. 27-7-1964)

²Subs. by s. 12, *ibid.*, for sub-section (1), (w.e.f. 27-7-64).

³Subs. by Act 13 of 1964, s. 11, for “the Schedule” (w.e.f. 15-9-1964).

⁴Subs. by Act 11 of 1955, s. 8, for “State Government.”

(f) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular; or

(g) if the label or container bears the name of an individual or company purporting to be the manufacturer or producer of the drug, which individual or company is fictitious or does not exist.

¹[17A. *Misbranded cosmetics*.—For the purposes of this Chapter, a cosmetic shall be deemed to be misbranded—

(a) if it is an imitation of, or a substitute for, or resembles in a manner likely to deceive, another cosmetic; or

(b) if it purports to be the product of a place or country of which it is not truly a product; or

(c) if it contains a colour which is not prescribed; or

(d) if it is sold, or offered or exposed for sale, under a name which belongs to another cosmetic; or

(e) if it is not labelled in the prescribed manner; or

(f) if its label or container bears the name of an individual or company purporting to be the manufacturer or producer of the cosmetic which individual or company is fictitious or does not exist; or

(g) if the label or container bears any statement which is false or misleading in any particular.]

²[17B. *Adulterated drugs*.—For the purposes of this Chapter a drug shall be deemed to be adulterated—

(a) if it consists, in whole or in part, of any filthy, putrid or decomposed substance; or

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) if any substance has been—

(i) mixed or packed therewith so as to reduce its quality or strength; or

(ii) substituted wholly or in part therefor.

¹Ins. by Act 21 of 1962, s. 13 (w.e.f. 27-7-1964).

²Ins. by Act 13 of 1964, s. 12 (w.e.f. 15-9-1964).

Explanation.—For the purpose of clause (a), a drug shall not be deemed to consist, in whole or in part, of any decomposed substance only by reason of the fact that such decomposed substance is the result of any natural decomposition of the drug within the period, if any, specified on the label of the drug within which the drug is to be used :

Provided that such decomposition is not due to any negligence on the part of the manufacturer of the drug or the dealer thereof and that it does not render the drug injurious to health.]

18. *Prohibition of manufacture and sale of certain drugs and cosmetics.*—From such ¹date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf—

(a) manufacture for sale, or sell, or stock or exhibit for sale, or distribute—

(i) any drug ²[or cosmetic] which is not of standard quality;

³[(ii) any misbranded drug or misbranded cosmetic;]

⁴[(iii) any adulterated drug;]

⁵[(iv) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of ingredients contained in it in a manner readily intelligible to the members of the medical profession;]

(v) any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims ⁶[to prevent, cure or mitigate] any such disease or ailment, or to have any such other effect as may be prescribed;

⁷[(vi) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;

(vii) any drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made thereunder;]

(b) sell, or stock or exhibit for sale, or distribute any drug ⁸[or cosmetic] which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made thereunder;

¹1st April, 1947 for sub-clauses (i), (ii), (iv) and (v) of clause (a) and clauses (b) and (c); 1st April, 1949 for sub-clause (iii) of clause (a) in so far as it takes effect in Delhi, Ajmer and Coorg, see Notification No. 18-12/46-D. II, dated 11th February, 1947. Gazette of India, 1947, Pt. I, p. 189; as amended by Notification No. F. 1-2/48-D(II), dated 29th September, 1948; 1st April, 1953 for the States of Himachal Pradesh, Bilaspur, Kutch, Bhopal, Tripura, Vindhya Pradesh and Manipur, vide Notification No. S.R.O. 664, dated 30th March, 1953, Gazette of India, 1953, Pt. II, Sec. 3, p. 451.

²Ins. by Act 21 of 1962, s. 14 (w.e.f. 27-7-1964).

³Subs. by s. 14, *ibid.*, for sub-clause (ii) (w.e.f. 27-7-1964).

⁴Ins. by Act 13 of 1964, s. 13 (w.e.f. 15-9-1964).

⁵Subs. by Act 11 of 1955, s. 9, for sub-clause (iii).

⁶Subs. by s. 9, *ibid.*, for "to cure or mitigate".

⁷Subs. by Act 21 of 1962, s. 14, for sub-clause (v) (w.e.f. 27-7-1964).

⁸Ins. by s. 14, *ibid.* (w.e.f. 27-7-1964).

(c) manufacture for sale, or sell, or stock or exhibit for sale, or distribute any drug [or cosmetic], except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter.

Provided that nothing in this section shall apply to the manufacture, subject to prescribed condition of small quantities of any drug for the purpose of examination, test or analysis.

Provided further that the ²[Central Government] may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the manufacture for sale, sale or distribution of any drug or class of drugs not being of standard quality.

Explanation.—The formula or list of ingredients mentioned in sub-clause (iii) of clause (a) shall be deemed to be true and a sufficient compliance with that sub-clause if, without disclosing a full and detailed recipe of the ingredients, it indicates correctly all the potent or poisonous substances contained therein together with an approximate statement of the composition of the medicine.

³[18A. Disclosure of the name of the manufacturer, etc.—Every person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall, if so required, disclose to the Inspector the name, address and other particulars of the person from whom he acquired the drug or cosmetic.]

19. Pleas.—(1) Save as hereinafter provided in this section, it shall be no defence in a prosecution under this Chapter to prove merely that the accused was ignorant of the nature, substance or quality of the drug [or cosmetic] in respect of which the offence has been committed or of the circumstances of its manufacture or import, or that a purchaser, having bought only for the purpose of test or analysis, has not been prejudiced by the sale.

(2) [For the purposes of section 18 a drug shall not be deemed to be misbranded or adulterated or to be below standard quality nor shall a cosmetic be deemed to be misbranded or to be below standard quality] only by reason of the fact that—

(a) there has been added thereto some innocuous substance or ingredient because the same is required for the manufacture or preparation of the drug [or cosmetic] as an article of commerce in a state fit for carriage or consumption, and not to increase the bulk, weight or measure of the drug [or cosmetic] or to conceal its inferior quality or other defects; or

¹Ins. by Act 21 of 1962, s. 15 (w.e.f. 25-7-1964).

²Subs. by Act 11 of 1965, s. 4 (w.e.f. 1-1-1966).

³Ins. by Act 13 of 1961, s. 15 (w.e.f. 1-1-1962).

⁴Ins. by Act 21 of 1962, s. 15 (w.e.f. 25-7-1964).

⁵Subs. by Act 13 of 1961, s. 15, for certain words (w.e.f. 1-1-1962).

(b) in the process of manufacture, preparation or conveyance some extraneous substance has unavoidably become intermixed with it. Provided that this clause shall not apply in relation to any sale or distribution of the drug [or cosmetic] occurring after the vendor or distributor became aware of such intermixture.

(5) A person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall not be liable for a contravention of section 18 if he proves—

(a) that he acquired the drug or cosmetic from a duly licensed manufacturer, distributor or dealer thereof;

(b) that he did not know and could not, with reasonable diligence, have ascertained that the drug or cosmetic in any way contravened the provisions of that section; and

(c) that the drug or cosmetic, while in his possession, was properly stored and remained in the same state as when he acquired it.]

⁴[20. *Government Analysts*.—(1) The State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts for such areas in the State and in respect of such drugs or ⁵[classes of drugs or such cosmetics or classes of cosmetics] as may be specified in the notification.

(2) The Central Government may also, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts in respect of such drugs or ⁵[classes of drugs or such cosmetics or classes of cosmetics] as may be specified in the notification.

(3) Notwithstanding anything contained in sub-section (1) or sub-section (2), neither the Central Government nor a State Government shall appoint as a Government Analyst any official not serving under it without the previous consent of the Government under which he is serving.

21. *Inspectors*.—(1) The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Inspectors for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.

(2) The powers which may be exercised by an Inspector and the duties which may be performed by him, the drugs or ⁶[classes of drugs or cosmetics or classes of cosmetics] in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed shall be such as may be prescribed.

⁴Ch. I inserted by Act 11 of 1955, s. 10(16) and by Act 13 of 1964, s. 15 (w.e.f. 15-9-1964).

²Ins. by Act 21 of 1962, s. 15 (w.e.f. 27-7-1964).

³Subs. by Act 13 of 1964, s. 15, for sub-section (3) (w.e.f. 15-9-1964).

⁴Subs. by Act 35 of 1960, s. 4, for the original ss. 20 and 21 (w.e.f. 16-3-1961).

⁵Subs. by Act 21 of 1962, s. 16, for "class of drugs" (w.e.f. 27-7-1964).

⁶Subs. by s. 17, *ibid.*, for "class of drugs" (w.e.f. 27-7-1964).

(3) No person who has any financial interest ¹[in the import, manufacture or sale of drugs or cosmetics] shall be appointed to be an Inspector under this section.

(4) Every Inspector shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code (45 of 1860), and shall be officially subordinate to such authority as the Government appointing him may specify in this behalf.]

²[22. Powers of Inspectors.—(1) Subject to the provisions of section 23 and of any rules made by the Central Government in this behalf, an Inspector may, within the local limits of the area for which he is appointed,—

(a) inspect any premises wherein any drug ³[or cosmetic] is being manufactured and in the case of sera, vaccines and any other drug prescribed in this behalf, the plant and process of manufacture and the means employed for standardizing and testing the drug;

(b) take samples of any drug ³[or cosmetic] which is being manufactured, or being sold or is stocked or exhibited for sale, or is being distributed;

(c) enter and search at all reasonable times, with such assistants, if any, as he considers necessary, any place in which he has reason to believe that an offence under this Chapter has been or is being committed and order in writing the person in possession of any drug ³[or cosmetic] in respect of which the offence has been or is being committed, not to dispose of any stock of such drug ³[or cosmetic] for a specified period not exceeding twenty days, or, unless the alleged offence is such that the defect may be removed by the possessor of the drug ³[or cosmetic], seize the stock of such drug ³[or cosmetic];

⁴[(cc) examine any record, register, document or any other material object found in any place mentioned in clause (c), and seize the same if he has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act or the Rules made thereunder;]

(d) exercise such other powers as may be necessary for carrying out the purposes of this Chapter or any rules made thereunder.

(2) The provisions of the Code of Criminal Procedure, 1898 (5 of 1898) shall, so far as may be, apply to any search or seizure under this Chapter as they apply to any search or seizure made under the authority of a warrant issued under section 98 of the said Code.

¹Subs. by Act 21 of 1962, s. 17, for "in the manufacture, import or sale of drugs" (w.e.f. 27-7-1964).

²Subs. by Act 11 of 1955, s. 11, for s. 22.

³Ins. by Act 21 of 1962, s. 18 (w.e.f. 27-7-1964).

⁴Ins. by Act 35 of 1960, s. 5 (w.e.f. 16-3-1961).

(3) If any person wilfully obstructs an Inspector in the exercise of the powers conferred upon him by or under this Chapter, he shall be punishable with imprisonment which may extend to three years, or with fine, or with both.]

23. *Procedure of Inspectors.*—(1) Where an Inspector takes any sample of a drug ¹[or cosmetic] under this Chapter, he shall tender the fair price thereof and may require a written acknowledgement therefor.

(2) Where the price tendered under sub-section (1) is refused, or where the Inspector seizes the stock of any drug ¹[or cosmetic] under clause (c) of section 22, he shall tender a receipt therefor in the prescribed form.

(3) Where an Inspector takes a sample of a drug ¹[or cosmetic] for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he wilfully absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so sealed and marked.

Provided that where the sample is taken from premises whereon the drug ¹[or cosmetic] is being manufactured, it shall be necessary to divide the sample into three portions only :

Provided further that where the drug ¹[or cosmetic] is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the drug ¹[or cosmetic] be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or four, as the case may be, of the said containers after suitably marking the same and, where necessary, sealing them.

(4) The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall retain the remainder and dispose of the same as follows :—

(i) one portion or container he shall forthwith send to the Government Analyst for test or analysis;

(ii) the second he shall produce to the Court before which proceedings, if any, are instituted in respect of the drug ¹[or cosmetic]; and

²[(iii) the third, where taken, he shall send to the person, if any, whose name, address and other particulars have been disclosed under section 18A.]

¹Ins. by Act 21 of 1962, s. 15 (w.e.f. 27-7-1964).

²Subs. by Act 13 of 1964, s. 16, for cl. (iii) (w.e.f. 15-9-1964).

(5) Where an Inspector takes any action under clause (a) of section 22,—

(a) he shall use all despatch in ascertaining whether or not the drug ¹[or cosmetic] contravenes any of the provisions of section 18 and, if it is ascertained that the drug ¹[or cosmetic] does not, so contravene forthwith revoke the order passed under the said clause or, as the case may be, take such action as may be necessary for the return of the stock seized;

(b) if he seizes the stock of the drug ¹[or cosmetic], he shall as soon as may be, inform a Magistrate and take his orders as to the custody thereof;

(c) without prejudice to the institution of any prosecution, if the alleged contravention be such that the defect may be remedied by the possessor of the drug ¹[or cosmetic], he shall, on being satisfied that the defect has been so remedied, forthwith revoke his order under the said clause.

²[(6) Where an Inspector seizes any record, register, document or any other material object under clause (cc) of sub-section (1) of section 22, he shall, as soon as may be, inform a magistrate and take his orders as to the custody thereof.]

24. *Persons bound to disclose place where drugs or cosmetics are manufactured or kept.*—Every person for the time being in charge of any premises whereon any drug ¹[or cosmetic] is being manufactured or is kept for sale or distribution shall, on being required by an Inspector so to do, be legally bound to disclose to the Inspector the place where the drug ¹[or cosmetic] is being manufactured or is kept, as the case may be.

25. *Reports of Government Analysts.*—(1) The Government Analyst to whom a sample of any drug ¹[or cosmetic] has been submitted for test or analysis under sub-section (4) of section 23, shall deliver to the Inspector submitting it a signed report in triplicate in the prescribed form.

(2) The Inspector on receipt thereof shall deliver one copy of the report to the person from whom the sample was taken ³[and another copy to the person, if any, whose name, address and other particulars have been disclosed under section 18A], and shall retain the third copy for use in any prosecution in respect of the sample.

(3) Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence of the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken ⁴[or the person whose name, address and other particulars have been disclosed under section 18A] has, within twenty-eight days of the receipt of a copy of the report, notified in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.

¹Ins by 21 of 1962 s. 15 (w.e.f. 27-7-1964)

²Ins. by Act 35 of 1960, s. 6 (w.e.f. 16-3-1961).

³Subs. by Act 13 of 1964, s. 17, for certain words (w.e.f. 15-9-1964).

⁴Subs. by s. 17, *ibid.*, for "or the said warrantor" (w.e.f. 15-9-1964).

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(4) Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst's report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused, cause the sample of the drug [or cosmetic] produced before the Magistrate under sub-section (4) of section 3 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by, or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein.

(5) The cost of a test or analysis made by the Central Drugs Laboratory under sub-section (4) shall be paid by the complainant or accused as the Court shall direct.

26. *Purchaser of drug or cosmetic enabled to obtain test or analysis.*—Any person shall, on application in the prescribed manner and on payment of the prescribed fee, be entitled to submit for test or analysis to a Government Analyst any drug [or cosmetic] purchased by him and to receive a report of such test or analysis signed by the Government Analyst.

27. *Penalty for manufacture, sale, etc., of drugs in contravention of this Chapter.*—Whoever himself or by any other person on his behalf manufactures for sale, sells, stocks or exhibits for sale or distributes—

(a) any drug—
(i) deemed to be misbranded under clause (a), clause (b), clause (c), clause (d), clause (f) or clause (g) of section 17 or adulterated under section 17B; or

(ii) without a valid licence as required under clause (c) of section 18.

shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to ten years and shall also be liable to fine.

Provided that the Court may, for any special reasons to be recorded in writing, impose a sentence of imprisonment of less than one year;

(b) any drug other than a drug referred to in clause (a) in contravention of any of the provisions of this Chapter or any rule made thereunder shall be punishable with imprisonment for a term which may extend to three years, or with fine, or with both.]

27A. *Penalty for manufacture, sale, etc., of cosmetics in contravention of this Chapter.*—Whoever himself or by any other person on his behalf manufactures for sale, sells, stocks or exhibits for sale or distributes any cosmetic in contravention of any of the provisions of this Chapter or any rule made thereunder, shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to five hundred rupees, or with both.]

¹Ins. by Act 21 of 1962, s. 15 (w.e.f. 27-7-1964).

²Subs. by Act 13 of 1964, s. 18, for s. 27 (w.e.f. 15-9-1964).

³Ins. by Act 21 of 1962, s. 19 (w.e.f. 27-7-1964.)

¹[28. *Penalty for non-disclosure of the name of the manufacturer, etc.*—Whoever contravenes the provisions of section 18A shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to five hundred rupees, or with both.]

29. *Penalty for use of Government Analyst's report for advertising.*—Whoever uses any report of a test or analysis made by the Central Drugs Laboratory or by a Government Analyst, or any extract from such report, for the purpose of advertising any drug ²[or cosmetic], shall be punishable with fine which may extend to five hundred rupees.

³[30. *Penalty for subsequent offences.* ⁴[(1) Whoever, having been convicted of an offence—

(a) under clause (a) of section 27 is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to ⁵[ten years] and shall also be liable to fine :

Provided that the Court may, for any special reasons to be recorded in writing, impose a sentence of less than two years;

(b) under clause (b) of section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which may extend to ⁵[ten years], or with fine, or with both.]

⁶[(1A) Whoever, having been convicted of an offence under section 27A is again convicted under that section, shall be punishable with imprisonment for a term which may extend to two years, or with fine which may extend to one thousand rupees, or with both.]

(2) Whoever, having been convicted of an offence under ⁷* * * section 29 is again convicted of an offence under the same section shall be punishable with imprisonment which may extend to ⁸[ten years] or with fine, or with both.]

31. *Confiscation.* ⁹[(1)] Where any person has been convicted under this Chapter for contravening any such provision of this Chapter or any rule made thereunder as may be specified by rule made in this behalf, the stock of the drug ¹⁰[or cosmetic] in respect of which the contravention has been made shall be liable to confiscation ¹¹[and if such contravention is in respect of—

¹Subs. by Act 13 of 1964, s. 19, for s. 28 (w.e.f. 15-9-1964).

²Ins by Act 21 of 1962, s. 15 (w.e.f. 27-7-1964)

³Subs. by Act 11 of 1955, s. 14, for s. 30.

⁴Subs. by Act 35 of 1960, s. 8, for sub-section (1) (w.e.f. 16-3-1961).

⁵Subs. by Act 13 of 1964, s. 20, for "five years" (w.e.f. 15-9-1964).

⁶Ins. by Act 21 of 1962, s. 20 (w.e.f. 27-7-1964).

⁷The words and figures "section 28 or" omitted by Act 13 of 1964, s. 20 (w.e.f. 15-9-1964).

⁸Subs. by s. 20, *ibid.*, for "two years".

⁹Re-numbered as sub-section (1) by Act 35 of 1960, s. 9 (w.e.f. 16-3-1961).

¹⁰Ins. by Act 21 of 1962, s. 21 (w.e.f. 27-7-1964).

¹¹Added by Act 13 of 1964, s. 21 (w.e.f. 15-9-1964).

(i) manufacture of any drug deemed to be misbranded under clause (a), clause (b), clause (c), clause (d), clause (f) or clause (g) of section 17 or adulterated under section 17B; or

(ii) manufacture for sale, or sale, or stocking or exhibiting for sale, or distribution of any drug without a valid licence as required under clause (c) of section 18,

any implements or machinery used in such manufacture, sale or distribution and any receptacles, packages or coverings in which such drug is contained and the animals, vehicles, vessels or other conveyances used in carrying such drug shall also be liable to confiscation].

¹[(2) Without prejudice to the provisions contained in sub-section (1) where the Court is satisfied, on the application of an Inspector or otherwise and after such inquiry as may be necessary that the drug or cosmetic is not of standard quality ²[or is a misbranded or adulterated drug], or misbranded cosmetic, such drug or, as the case may be, such cosmetic shall be liable to confiscation].

³[31A. *Application of provisions to Government departments.*—The provisions of this Chapter except those contained in section 31 shall apply in relation to the manufacture, sale or distribution of drugs by any department of Government as they apply in relation to the manufacture, sale or distribution of drugs by any other person.]

32. *Cognizance of offences.*—(1) No prosecution under this Chapter shall be instituted except by an Inspector.

(2) No Court inferior to that of a Presidency Magistrate or of a Magistrate of the first class shall try an offence punishable under this Chapter.

(3) Nothing contained in this Chapter shall be deemed to prevent any person from being prosecuted under any other law for any act or omission which constitutes an offence against this Chapter.

⁴[32A. *Power of Court to implead the manufacturer, etc.*—Where, at any time during the trial of any offence under this Chapter alleged to have been committed by any person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof the Court is satisfied, on the evidence adduced before it, that such manufacturer or agent is also concerned in that offence, then, the Court may, notwithstanding anything contained in sub-section (1) of section 351 of the Code of Criminal Procedure, 1898 (5 of 1898) proceed against him as though a prosecution had been instituted against him under section 32.]

33. ⁵[*Power of Central Government to make rules.*—(1) The Central Government may after consultation with the Board and after previous publication by notification in the Official Gazette, make rules for the purposes of giving effect to the provisions of this Chapter :

¹Ins. by Act 21 of 1962 s. 18 (w.e.f. 27-7-1964).

²Ins. by Act 35 of 1960 s. 5 (w. e. f. 16-3-1961).

³Ins. by Act 13 of 1964, s. 22 (w.e.f. 15-9-1964).

⁴Ins. by s. 23, *ibid* (w.e.f. 15-9-1964).

⁵Subs. by Act 11 of 1955, s. 15, for sub-section (1).

Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.]

(2) Without prejudice to the generality of the foregoing power, such rules may—

(a) provide for the establishment of laboratories for testing and analysing drugs ¹[or cosmetics];

(b) prescribe the qualifications and duties of Government Analysts and the qualifications of Inspectors;

(c) prescribe the methods of test or analysis to be employed in determining whether a drug ¹[or cosmetic] is of standard quality;

(d) prescribe, in respect of biological and organometallic compounds, the units or methods of standardisation;

²[(dd) prescribe under clause (d) of section 17B the colour or colours which a drug may bear or contain for purposes of colouring;]

(e) prescribe the forms of licences for the manufacture for sale, for the sale and for the distribution of drugs or any specified drug or class of drugs ¹[or of cosmetics or any specified cosmetic or class of cosmetics], the form of application for such licences, the conditions subject to which such licences may be issued, the authority empowered to issue the same and the fees payable therefor;

(f) specify the diseases or ailments which a drug may not purport or claim ³[to prevent, cure or mitigate] and such other effects which a drug may not purport or claim to have;

(g) prescribe the conditions subject to which small quantities of drugs may be manufactured for the purpose of examination, test or analysis;

(h) require the date of manufacture and the date of expiry of potency to be clearly and truly stated on the label or container of any specified drug or class of drugs, and prohibit the sale, stocking or exhibition for sale, or distribution of the said drug or class of drugs after the expiry of a specified period from the date of manufacture or after the expiry of the date of potency;

(i) prescribe the conditions to be observed in the packing in bottles packages, and other containers of drugs ¹[or cosmetics], and prohibit the sale, stocking or exhibition for sale, or distribution of drugs ¹[or cosmetics] packed in contravention of such conditions;

¹Ins. by Act 21 of 1962, s. 22 (w.e.f. 27-7-1964).

²Ins. by Act 13 of 1964, s. 24 (w.e.f. 15-9-1964).

³Subs. by Act 11 of 1955, s. 15, for "to cure or mitigate".

(j) regulate the mode of labelling packed drugs ¹[or cosmetics], and prescribe the matters which shall or shall not be included in such labels;

(k) prescribe the maximum proportion of any poisonous substance which may be added to or contained in any drug, prohibit the manufacture, sale or stocking or exhibition for sale, or distribution of any drug in which that proportion is exceeded, and specify substances which shall be deemed to be poisonous for the purposes of this Chapter and the rules made thereunder;

(l) require that the accepted scientific name of any specified drug shall be displayed in the prescribed manner on the label or wrapper of any patent or proprietary medicine containing such drug;

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³[(n) prescribe the powers and duties of Inspectors and ⁴[specify the drugs or classes of drugs or cosmetics or classes of cosmetics] in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed;]

(o) prescribe the forms of report to be given by Government Analysts, and the manner of application for test or analysis under section 26 and the fees payable therefor;

⁵[(p) specify the offences against this Chapter or any rule made thereunder in relation to which an order of confiscation may be made under section 31; and]

(q) provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter or the rules made thereunder, of any specified drug or class of drugs ¹[or cosmetic or class of cosmetics];

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⁷[33A. *Chapter not to apply to Ayurvedic (including Siddha) or Unani drugs.*—Save as otherwise provided in this Act, nothing contained in this Chapter shall apply to Ayurvedic (including Siddha) or Unani drugs.]

⁸[CHAPTER IVA

PROVISIONS RELATING TO AYURVEDIC (INCLUDING SIDDHA) AND UNANI DRUGS

33B. *Application of Chapter IVA*—This Chapter shall apply only to Ayurvedic (including Siddha) and Unani drugs.

¹Ins by Act 21 of 1962, s.22 (w.e.f. 27-7-1964).

²Cl. (m) omitted by Act 13 of 1964, s. 24 (w.e.f. 15-9-1964).

³Subs. by Act 35 of 1960, s. 10, for cl. (n) (w.e.f. 16-3-1961).

⁴Subs. by Act 21 of 1962, s. 22, for "the drugs or class of drugs" (w.e.f. 27-7-1964).

⁵Subs. by Act 13 of 1964, s. 24, for cl. (p) (w.e.f. 15-9-1964).

⁶Sub-section (3) ins. by Act 35 of 1960, omitted by Act 13 of 1964, s.24 (w.e.f. 15-9-1964).

⁷Ins. by Act 13 of 1964, s. 25 (w.e.f. 1-2-1969).

⁸Ins. by Act 13 of 1964, s. 26, (w.e.f. 8-12-1969).

33C. *Ayurvedic and Unani Drugs Technical Advisory Board*.—(1) The Central Government shall, by notification in the Official Gazette and with effect from such date as may be specified therein, constitute a Board (to be called the Ayurvedic and Unani Drugs Technical Advisory Board) to advise the Central Government and the State Governments on technical matters arising out of this Chapter and to carry out the other functions assigned to it by this Chapter.

(2) The Board shall consist of the following members, namely :—

- (i) the Director General of Health Services, *ex officio*;
- (ii) the Drugs Controller, India *ex officio*;
- (iii) the Adviser in indigenous systems of medicine, Ministry of Health, *ex officio*;
- (iv) the Director of the Central Drugs Laboratory, Calcutta, *ex officio*;
- (v) one person holding the appointment of Government Analyst under section 33F, to be nominated by the Central Government;
- (vi) one Pharmacognocist to be nominated by the Central Government;
- (vii) one Phyto-chemist to be nominated by the Central Government;
- (viii) two persons to be nominated by the Central Government from among members of the Central Council of Ayurvedic Research;
- (ix) one teacher in Dravyaguna and Bhaishajya Kalpana, to be nominated by the Central Government;
- (x) one teacher in Ilm-Ul-Advia and Taklis-Wa-Dawa-sazi, to be nominated by the Central Government;
- (xi) two persons, one each to represent the Ayurvedic (including Siddha) and Unani drug industry, to be nominated by the Central Government;
- (xii) two persons, one each from among the practitioners of Ayurvedic (including Siddha) and Unani systems of medicine, to be nominated by the Central Government.

(3) The Central Government shall appoint a member of the Board as its Chairman.

(4) The nominated members of the Board shall hold office for three years but shall be eligible for renomination.

(5) The Board may, subject to the previous approval of the Central Government, make bye-laws fixing a quorum and regulating its own procedure and conduct of all business to be transacted by it.

(6) The functions of the Board may be exercised notwithstanding any vacancy therein.

(7) The Central Government shall appoint a person to be Secretary of the Board and shall provide the Board with such clerical and other staff as the central government considers necessary.

33D. *Prohibition of manufacture for sale of Ayurvedic (including Siddha) and Unani drugs.* From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf no person shall himself or by any other person on his behalf, manufacture for sale any Ayurvedic (including Siddha) or Unani drug,—

- (a) except under prescribed hygienic conditions;
- (b) except under the supervision of a person having the prescribed qualifications;
- (c) except under and in accordance with the conditions of a licence issued for such purpose under this Chapter;
- (d) unless the raw materials used in the preparation of such drug are genuine and are properly identified;
- (e) unless such drug is labelled with the true list of all the ingredients contained in it and with such other particulars as may be prescribed; and
- (f) in contravention of any of the provisions of this Chapter or any rule made thereunder :

Provided that nothing in this section shall apply to Vaidyas and Hakims who manufacture such drugs for the use of their own patients :

Provided further that nothing in clauses (a), (b) and (c) shall apply to the manufacture, subject to prescribed conditions, of small quantities of any such drug for the purpose of examination, test or analysis.

33E. *Restriction on sale, etc. of Ayurvedic (including Siddha) and Unani drugs.* From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf, sell, or stock or exhibit for sale, or distribute, any Ayurvedic (including Siddha) or Unani drug other than that manufactured by a manufacturer licensed under this Chapter.

33F. *Government Analysts.*—(1) The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.

(2) Notwithstanding anything contained in sub-section (1), neither the Central Government nor a State Government shall appoint as a Government Analyst any official not serving under it without the previous consent of the Government under which he is serving.

33G. *Inspectors.*—(1) The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Inspectors for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.

(2) The powers which may be exercised by an Inspector and the duties which may be performed by him and the conditions, limitations or restrictions subject to which such powers and duties may be exercised or performed shall be such as may be prescribed.

(3) No person who has any financial interest in the manufacture or sale of any drug shall be appointed to be an Inspector under this section.

(4) Every Inspector shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code (45 of 1860) and shall be officially subordinate to such authority as the Government appointing him may specify in this behalf.

33H. *Application of provisions of sections 22, 23, 24 and 25.* The provisions of sections 22, 23, 24 and 25 and the rules, if any, made thereunder shall, so far as may be, apply in relation to an Inspector and a Government Analyst appointed under this Chapter as they apply in relation to an Inspector and a Government Analyst appointed under Chapter IV, subject to the modification that the references to "drug" in the said sections, shall be construed as references to "Ayurvedic (including Siddha) or Unani Drug."

33I. *Penalty for manufacture, sale, etc., of Ayurvedic (including Siddha) and Unani drugs in contravention of this Chapter.* Whoever contravenes the provisions of section 33D or section 33E or section 24 as applied by section 33H or any rule made under this Chapter shall be punishable with imprisonment for a term which may extend to three months, or with fine which may extend to five hundred rupees, or with both.

33J. *Penalty for subsequent offences.* Whoever, having been convicted of an offence under section 33D or section 33E is again convicted of an offence under the said section shall be punishable with imprisonment for a term which may extend to six months, or with fine which may extend to one thousand rupees, or with both.

33K. *Confiscation.* Where any person has been convicted under this Chapter, the stock of the Ayurvedic (including Siddha) or Unani drug, in respect of which the contravention has been made, shall be liable to confiscation.

33L. *Application of provisions to Government departments.* The provisions of this Chapter except those contained in section 33K shall apply in relation to the manufacture for sale, sale, or distribution of any Ayurvedic (including Siddha) or Unani drug by any department of Government as they apply in relation to the manufacture for sale, sale, or distribution of such drug by any other person.

33M. *Cognizance of offences.*—(1) No prosecution under this Chapter shall be instituted except by an Inspector.

(2) No Court inferior to that of a Presidency Magistrate or of a Magistrate of the first class shall try an offence punishable under this Chapter.

33N. *Power of Central Government to make rules.*—(1) The Central Government may, after consultation with the Board and after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter :

Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which

render it necessary to make rules without such consultation, but in such a case, the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.

(2) Without prejudice to the generality of the foregoing power, such rules may—

(a) provide for the establishment of laboratories for testing and analysing Ayurvedic (including Siddha) or Unani drugs;

(b) prescribe the qualification and duties of Government Analysts and the qualifications of Inspectors;

(c) prescribe the methods of test or analysis to be employed in determining whether any Ayurvedic (including Siddha) or Unani drug is labelled with the true list of the ingredients which it is purported to contain;

(d) specify any substance as a poisonous substance;

(e) prescribe the forms of licences for the manufacture for sale of Ayurvedic (including Siddha) or Unani drugs, the form of application for such licences, the conditions subject to which such licences may be issued, the authority empowered to issue the same and the fees payable therefor;

(f) regulate the mode of labelling packed Ayurvedic (including Siddha) or Unani drugs and prescribe the matters which shall or shall not be included in such labels;

(g) prescribe the conditions subject to which small quantities of Ayurvedic (including Siddha) or Unani drugs may be manufactured for the purpose of examination, test or analysis; and

(h) any other matter which is to be or may be prescribed under this Chapter.

33O. *Power to amend First Schedule.* The Central Government, after consultation with the Board and after giving, by notification in the Official Gazette, not less than three months' notice of its intention so to do, may, by a like notification, add to or otherwise amend the First Schedule for the purposes of this Chapter and thereupon the said Schedule shall be deemed to be amended accordingly.]

¹[CHAPTER V

MISCELLANEOUS

²[33P.] *Power to give directions.* The Central Government may give such directions to any State Government as may appear to the Central Go-

¹Subs. by Act 11 of 1955, s. 16, for s. 34.

²Ins. by Act 35 of 1960, s. 11 (w.e.f. 16-3-1961).

³S. 33A re-numbered as s. 33P by Act 13 of 1964, s. 27 (w.e.f. 15-9-1964).

vernment of be necessary for carrying into execution in the State any of the provisions of this Act or of any rule or order made thereunder.]

34. *Offences by companies.* (1) Where an offence under this Act has been committed by a company, every person who at the time the offence was committed, was in charge of, and was responsible to the company for the conduct of the business of the company, as well as the company shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly :

Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1), where an offence under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Explanation.—For the purposes of this section—

(a) “company” means a body corporate, and includes a firm or other association of individuals; and

(b) “director” in relation to a firm means a partner in the firm.

¹[34A. *Offences by Government departments.* Where an offence under Chapter IV or Chapter IVA has been committed by any department of Government, such authority as is specified by the Central Government to be in charge of manufacture, sale or distribution of drugs or where no authority is specified, the head of the department, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly :

Provided that nothing contained in this section shall render any such authority or person liable to any punishment provided in Chapter IV or Chapter IVA, as the case may be, if such authority or person proves that the offence was committed without its or his knowledge or that such authority or person exercised all due diligence to prevent the commission of such offence.]

35. *Publication of sentences passed under this Act.* (1) If any person is convicted of an offence under this Act, it shall be lawful for the Court before which the conviction takes place to cause the offender's name, place of residence, the offence of which he has been convicted and the penalty which has been inflicted upon him, to be published at the expense of such person in such newspapers or in such other manner as the Court may direct.

(2) The expenses of such publication shall be deemed to form part of the costs relating to the conviction and shall be recoverable in the same manner as those costs are recoverable.

¹Ins. by Act 13 of 1964, s. 28, (w.e.f. 15-9-1964).

36. *Magistrate's power to impose enhanced penalties.*—Notwithstanding anything contained ¹* * * the Code of Criminal Procedure, 1898, it shall be lawful for any Presidency Magistrate or any Magistrate of the first class to pass any sentence authorized by this Act in excess of his powers under ¹* * * the said Code.

37. *Protection of action taken in good faith.*—No suit, prosecution or other legal proceeding shall lie against any person for anything which is in good faith done or intended to be done under this Act.

²[38. *Rules to be laid before Parliament.*—Every rule made under this Act shall be laid as soon as may be after it is made before each House of Parliament while it is in session for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if before the expiry of the session in which it is so laid or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be, so however that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.]

¹ The words and figures "section 32 of" omitted by Act. 13 of 1964. 29, (w.e.f. 15-9-1964.)

² Ins. by s. 30, *ibid* (w.e.f. 15-9-1964).

[THE FIRST SCHEDULE

[See section 3(a)]

A.—AYURVEDIC (INCLUDING SIDDHA) SYSTEM

Serial No.

Name of book

Ayurveda

- | | |
|----|---|
| 1. | Arogya Kalpadruma |
| 2. | Arka Prakasha |
| 3 | Arya Bhishak |
| 4 | Ashtanga Hridaya |
| 5 | Ashtanga Samgraha |
| 6 | Ayurveda Kalpadruma |
| 7 | Ayurveda Prakasha |
| 8 | Ayurveda Samgraha |
| 9 | Bhaishajya Ratnavali |
| 10 | Brihat Bhaishajya Ratnakara |
| 11 | Bhava Prakasha |
| 12 | Brihat Nighantu Ratnakara |
| 13 | Charaka Samhita |
| 14 | Chakra Datta |
| 15 | Gada Nigraha |
| 16 | Kupi Pakva Rasayana |
| 17 | Nighantu Ratnakara |
| 18 | Rasa Chandanshu |
| 19 | Rasa Raja Sundara |
| 20 | Rasaratna Samuchaya |
| 21 | Rasatantra Sara Siddha Prayoga Samgraha |
| 22 | Rasa Tarangini |
| 23 | Rasa Yoga Sagara |
| 24 | Rasa Yoga Ratnakara |
| 25 | Rasa Yoga Samgraha |
| 26 | Rasendra Sara Samgraha |
| 27 | Rasa Pradipika |
| 28 | Sahasrayoga |

¹Subs. by Act 13 of 1964, s. 31, for the Schedule. First Schedule came into force w.e.f. 1-2-1969 and the Second Schedule came into force w.e.f. 15-9-1964.

The First Schedule

Serial No.	Name of book
29	Sarvaroga Chikitsa Ratnam
30	Sarvayoga Chikitsa Ratnam
31	Sharangadhara Samhita
32	Siddha Bhaishajya Manimala
33	Sidha Yoga Samgraha
34	Sushruta Samhita
35	Vaidya Chintamani
36	Vaidyaka Shabda Sindu
37	Vaidyaka Chikitsa Sara
38	Vaidya Jiwan
39	Vasava Rajeeyam
40	Yoga Ratnakara
41	Yoga Tarangini
42	Yoga Chintamani
43	Kashyapasamhita
44	Bhelasamhita
45	Vishwanathachikitsa
46	Vrindachikitsa
47	Ayurvedachintamani
48	Abhinavachintamani
49	Ayurveda-Ratnakar
50	Yogaratanasangraha
51	Rasamrita
52	Dravyagunanighantu
53	Rasamanijari
54	Bangasena

Sidha

55	Sidha Vaidya Thirattu
56	Therayar Maha Karisal
57	Brahma Muni Karukkadaï (300)
58	Bhogar (700)
59	Pulippani (500)
60	Agasthiyar Paripuranam (400)
61	Therayar Yamagam
62	Agasthiyar Chenduram (300)

The First Schedule

Serial No.	Name of book
63	Agasthiyar (1500)
64	Athmarakshamrutham
65	Agasthiyar Pin (80)
66	Agasthiyar Rathna Churukkam
67	Therayar Karisal (300)
68	Veeramamuni Nasa Kandam
69	Agasthiyar (600)
70	Agasthiyar Kanma Soothiram
71	18 Siddar's Chillarai Kovai
72	Yog Vatha Kaviyam
73	Therayar Tharu
74	Agasthiyar Vaidya Kaviyam (1500)
75	Bala Vagadam
76	Chimittu Rathna (Rathna) Churukkam
77	Nagamuni (200)
78	Agasthiyar Chillarai Kovai
79	Chikicha Rathna Deepam
80	Agasthiyar Nayana Vidhi
81	Yugi Karisal (151)
82	Agasthiyar Vallathi (600)
83	Therayar Thaila Varkam

B.—UNANI (TIBB) SYSTEM

Serial No.	Name of book
1	Karabadin Qadri
2	Karabadin Kabir
3	Karabadin Azam
4	Ilaj-ul-Amraz
5	Al Karabadin
6	Biaz Kabir Vol. II
7	Karabadin Jadid
8	Kitalf-ul-Taklis
9	Sanat-ul-Taklis
10	Mifta-ul-Khazain
11	Madan-ul-Aksir
12	Makhzan-ul-murabhat

THE SECOND SCHEDULE

(See sections 8 and 16)

STANDARDS TO BE COMPLIED WITH BY IMPORTED DRUGS AND BY DRUGS MANUFACTURED FOR SALE, SOLD, STOCKED OR EXHIBITED FOR SALE OR DISTRIBUTED

Class of drug	Standard to be complied with
1	2
1. Patent or proprietary medicines ¹ [other than Homoeopathic medicines]	The formula or list of ingredients displayed in the prescribed manner on the label or container and such other standards as may be prescribed.
2. Substances commonly known as vaccines, sera, toxin, toxoids, antitoxins, and antigens and biological products of such nature.	The standards maintained at the International Laboratory for Biological Standards, Statens Serum Institut, Copenhagen and such further standards of strength, quality and purity as may be prescribed.
3. Vitamins, hormones and analogous products.	The standards maintained at the International Laboratory for Biological Standards, National Institute for Medical Research, London, and such further standards of strength, quality and purity as may be prescribed.
4. Substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals.	Such standards as may be prescribed.
**4-A. Homeopathic Medicines :	
(a) Drugs included in the Homoeopathic Pharmacopoeia of India.	Standards of identity, purity and strength specified in the edition of the Homoeopathic Pharmacopoeia of India for the time being and such other standards as may be prescribed.
(b) Drugs not included in the Homoeopathic Pharmacopoeia of India, but which are included in the Homoeopathic Pharmacopoeia of United States of America or the United Kingdom or the German Homoeopathic Pharmacopoeia.	Standards of identity, purity and strength prescribed for the Drugs in the edition of such Pharmacopoeia for the time being in which they are given and such other standards as may be prescribed.
(c) Drugs not included in the Homoeopathic Pharmacopoeia of India or the United States of America, or the United Kingdom or the German Homoeopathic Pharmacopoeia.	The formula or list of ingredients displayed in the prescribed manner on the label of the container and such other standards as may be prescribed by the Central Government.

****Amended by Ministry of Health and Family Welfare Notification No. X-11014/3/77-D/M/S & PFA dated 6th June 1978.**

2[5. Other drugs

- (a) Drugs included in the Indian Pharmacopoeia.

Standards of identity, purity and strength specified in the edition of the Indian Pharmacopoeia for the time being in force and such other standards as may be prescribed.

In case the standards of identity purity and strength for drugs are not specified in the edition of the Indian Pharmacopoeia for the time being in force but are specified in the edition of the Indian Pharmacopoeia immediately preceding, the standards of identity, purity and strength shall be those occurring in such immediately preceding edition of the Indian Pharmacopoeia and such other standards as may [be prescribed.

- (b) Drugs not included in the Indian Pharmacopoeia but which are included in the official Pharmacopoeia of any other country.

Standards of identity, purity and strength specified for drugs in the edition of such official Pharmacopoeia of any other country for the time being in force and such other standards as may be prescribed.

In case the standards of identity, purity and strength for drugs are not specified in the edition of such official Pharmacopoeia for the time being in force, but are specified in the edition immediately preceding, the standards of identity, purity and strength shall be those occurring in such immediately preceding edition of such official Pharmacopoeia and such other standards as may be prescribed.]

¹Ins. by Notification No. S. O. 887, dated 19th March 1966, Gazette of India, Pt. II, Sec.3(ii), p. 819.

²Sub. by Notification No. G. S. R. 885 dated 18-8-73, Gazette of India Pt. II S.3(i)

औषधि और प्रसाधन सामग्री अधिनियम, 1940

धाराओं का क्रम

अध्याय 1

प्रारम्भिक

धाराएं

1. संक्षिप्त नाम, विस्तार और प्रारम्भ ।
2. अन्य विधियों के उपयोजन का वर्जित न होना ।
3. परिभाषाएं ।
- 3क. जम्मू-कश्मीर राज्य में अप्रवृत्त किसी विधि या अविद्यमान किसी कृत्यकारी के प्रति निर्देशों का अर्थान्वयन ।
4. विषले पदार्थों के बारे में उपधारणा ।

अध्याय 2

औषधि तकनीकी सलाहकार बोर्ड, केन्द्रीय औषधि द्रव्य प्रयोगशाला और औषधि परामर्श समिति

5. औषधि तकनीकी सलाहकार बोर्ड ।
6. केन्द्रीय औषधि प्रयोगशाला ।
7. औषधि परामर्श समिति ।
- 7क. (सिद्ध सहित) आयुर्वेदिक या यूनानी औषधियों को धारा 5 और 7 का लागू न होना ।

अध्याय 3

औषधियों का आयात

8. क्वालिटी मानक ।
9. मिथ्या छाप वाली औषधियां ।
- 9क. मिथ्या छाप वाली प्रसाधन सामग्रियां ।
- 9ख. अपमिश्रित औषधियां ।
10. कतिपय औषधियों या प्रसाधन सामग्रियों के आयात का प्रतिषेध ।

11. सागर सीमा-शुल्क से सम्बद्ध विधि का लागू होना और सीमा-शुल्क अधिकारियों की शक्तियाँ ।
12. नियम बनाने की केन्द्रीय सरकार की शक्ति ।
13. अपराध ।
14. अधिहरण ।
15. अधिकारिता ।

अध्याय 4

औषधियों का विनिर्माण, विक्रय और वितरण

16. क्वालिटी के मानक ।
17. मिथ्या छाप वाली औषधियाँ ।
- 17क. मिथ्या छाप वाली प्रसाधन सामग्री ।
- 17ख. अपमिश्रित औषधियाँ ।
18. कतिपय औषधियों या प्रसाधन सामग्रियों के विनिर्माण और विक्रय का प्रतिषेध ।
- 18क. विनिर्माता के नाम आदि का प्रकटन ।
19. अभिवाक ।
20. सरकारी विश्लेषक ।
21. निरीक्षक ।
22. निरीक्षकों की शक्तियाँ ।
23. निरीक्षकों की प्रक्रिया ।
24. व्यक्तियों का उस स्थान को प्रकट करने के लिए आबद्ध होना जहाँ औषधि या प्रसाधन सामग्रियाँ विनिर्मित की जाती या रखी जाती हैं ।
25. सरकारी विश्लेषकों की रिपोर्टें ।
26. औषधि या प्रसाधन सामग्री के क्रेता का परख या विश्लेषण कराने के लिए समर्थ होना ।
27. इस अध्याय के उल्लंघन में औषधियों के विनिर्माण, विक्रय आदि के लिए शास्ति ।
- 27क. इस अध्याय के उल्लंघन में प्रसाधन सामग्रियों के विनिर्माण, विक्रय आदि के लिए शास्ति ।
28. विनिर्माता आदि का नाम प्रकट न करने के लिए शास्ति ।
29. सरकारी विश्लेषक की रिपोर्ट का विज्ञापन के लिए उपयोग करने के लिए शास्ति ।
30. पश्चात्वर्ती अपराधों के लिए शास्ति ।
31. अधिहरण ।
- 31क. सरकारी विभागों को उपबंधों का लागू होना ।
32. अपराधों का संज्ञान ।
- 32क. विनिर्माता आदि को अभियोजित करने की न्यायालय की शक्ति ।

33. नियम बनाने की केन्द्रीय सरकार की शक्ति ।

33क. अध्याय का (सिद्ध सहित) आयुर्वेदिक या यूनानी औषधियों को लागू न होना ।

अध्याय 4क

(सिद्ध सहित) आयुर्वेदिक और यूनानी औषधियों से सम्बन्ध उपबन्ध

33ख. अध्याय 4क का लागू होना ।

33ग. आयुर्वेदिक और यूनानी औषधि तकनीकी सलाहकार बोर्ड ।

33घ. (सिद्ध सहित) आयुर्वेदिक और यूनानी औषधियों के विक्रयार्थ विनिर्माण का प्रतिषेध ।

33ङ. (सिद्ध सहित) आयुर्वेदिक और यूनानी औषधियों के विक्रय आदि पर निर्बंधन ।

33च. सरकारी विश्लेषक ।

33छ. निरीक्षक ।

33ज. धारा 22, 23, 24 और 25 के उपबन्धों का लागू होना ।

33झ. इस अध्याय के उन्मूलन में (सिद्ध सहित) आयुर्वेदिक और यूनानी औषधियों के विनिर्माण, विक्रय आदि के लिए शास्ति ।

33ञ. पश्चात्पूर्व अपराधों के लिए शास्ति ।

33ट. अधिहरण ।

33ठ. सरकारी विभागों को उपबन्धों का लागू होना ।

33ड. अपराधों का संज्ञान ।

33ढ. नियम बनाने की केन्द्रीय सरकार की शक्ति ।

33ण. प्रथम अनुसूची की संशोधित करने की शक्ति ।

अध्याय 5

प्रकीर्ण

33त. निदेश देने की शक्ति ।

34. कम्पनियों द्वारा अपराध ।

34क. सरकारी विभागों द्वारा अपराध ।

35. इस अधिनियम के अधीन पारित दण्डादेशों का प्रकाशन ।

36. वर्धित शास्तियां अधिरोपित करने की मजिस्ट्रेट की शक्ति ।

37. सद्भावपूर्वक की गई कार्रवाई के लिए परित्राण ।

38. नियमों का संसद् के समक्ष रखा जाना ।

प्रथम अनुसूची

द्वितीय अनुसूची

औषधि और प्रसाधन सामग्री अधिनियम 1940¹

(1940 का अधिनियम सं० 23)

[10 अप्रैल, 1940]

औषधियों²[और प्रसाधन सामग्रियों] के आयात, विनिर्माण, वितरण
और विक्रय को विनियमित करने के लिए
अधिनियम

यतः औषधियों²[और प्रसाधन सामग्रियों] के ³[आयात, विनिर्माण, वितरण और
विक्रय] को विनियमित करना समीचीन है ;

और यतः ऊपर वर्णित ऐसी बातों और उनकी आनुषंगिक बातों के लिए, जो भारत
शासन अधिनियम, 1935 की सातवीं अनुसूची की सूची 2 में प्रगणित की गई हैं,
सब प्रांतों के विधान-मंडलों ने उक्त अधिनियम की धारा 193 के निबन्धनों के अनुकूल
तकल्प पारित कर दिए हैं ;

अतः एतद्द्वारा निम्नलिखित रूप में यह अधिनियमित किया जाता है :—

अध्याय 1

प्रारम्भिक

1. संक्षिप्त नाम, विस्तार और प्रारम्भ : (1) यह अधिनियम औषधि ⁴[और
प्रसाधन सामग्री] अधिनियम, 1940 कहा जा सकेगा ।

(2) इसका विस्तार ⁵[जम्मू-कश्मीर राज्य के सिवाय] सम्पूर्ण भारत
पर है ।

1. उद्देश्य और कारणों को विवरणों के लिए सन् 1940 के राजपत्र के भाग 5, पृष्ठ 34 देखिए;
चयन समिति की रिपोर्ट के लिए इसी का पृष्ठ 143 देखिए । इस अधिनियम को उड़ीसा
राज्य में सभी अंशतः वर्जित क्षेत्रों में लागू किया गया, उड़ीसा राज्य सरकार की अधिसूचना
सं० 3358—स्थानीय स्वायत्त प्रशासन, दिनांक 25 अगस्त, 1941 देखिए ।
2. 1962 के अधिनियम सं० 21 की धारा 2 द्वारा 27-7-1964 से अन्तःस्थापित ।
3. विधि अनुकूलिकरण आदेश 1950 द्वारा कुछ शब्द प्रतिस्थापित ।
4. 1962 के अधिनियम सं० 21 की धारा 3 द्वारा 27-7-1964 से अन्तःस्थापित ।
5. 1972 के अधिनियम सं० 19 की धारा 2 द्वारा 'जम्मू-कश्मीर राज्य के सिवाय' शब्दों
का लोप किया गया ।

(3) यह तुरन्त प्रवृत्त होगा, किन्तु अध्याय 3 केवल उस ¹[तारीख] से प्रभावी होगा, जिसे केन्द्रीय सरकार राजपत्र में अधिसूचना द्वारा इस निमित्त नियत करे और अध्याय 4 राज्य विशेष में उस ही तारीख से प्रभावी होगा जिसे वह राज्य सरकार वैसी ही अधिसूचना द्वारा इस निमित्त नियत करे।

²["परन्तु जम्मू-कश्मीर राज्य के सम्बन्ध में अध्याय 3, औषधि और प्रसाधन सामग्री (संशोधन) अधिनियम, 1972 के प्रारम्भ के पश्चात् उसी तारीख से प्रभावी होगा, जिसे केन्द्रीय सरकार राज्यपत्र में अधिसूचना द्वारा, इस निमित्त नियत करे।"]

2. अन्य विधियों के उपयोजन का वर्जित न होना : इस अधिनियम के उपबन्ध अनिष्टकर मादक द्रव्य अधिनियम, 1930 (1930 का 2) और तत्समय प्रवृत्त किसी अन्य विधि के परिवर्धन में न कि उसके अल्पीकरण में, होंगे।

3. परिभाषाएं : इस अधिनियम में जब तक कि कोई बात विषय या संदर्भ में विरुद्ध न हो,—

³[(क) "(सिद्ध सहित) आयुर्वेदिक या यूनानी औषधि" के अन्तर्गत वे सब औषधि हैं जो मनुष्यों में रोग के निदान, उपचार, शमन या निवारण के लिए उसमें आन्तरिक या बाह्य उपयोग के लिए आशियत हैं और जो प्रथम अनुसूची में विनिर्दिष्ट (सिद्ध सहित) आयुर्वेदिक और यूनानी (तिब्ब) औषधि प्रणालियों की प्रामाणिक पुस्तकों में उल्लिखित हैं तथा उनमें वर्णित फारमूलों के अनुसार अनन्य रूप से प्रसंस्कृत और विनिर्मित हैं;]

1. 1 अप्रैल, 1947 से, देखिए अधिसूचना सं० रु० 28 (10) (3) 45-एच (आई) दिनांक 2-9-1946; 1946 का भारत का राजपत्र भाग-1 पृष्ठ 1349। अध्याय 4, दिल्ली, अजमेर और कुर्ग राज्यों में 1 अप्रैल, 1947 से प्रवृत्त हुआ, देखिए यथोक्त, अध्याय 3 और 4 हिमाचल प्रदेश बिलासपुर, कच्छ, भोपाल त्रिपुरा; विन्ध्य प्रदेश और मणिपुर राज्यों में 1 अप्रैल, 1953 से प्रवृत्त हुए देखिए अधिसूचना सं० 663 दिनांक 30-3-1953, भारत के राजपत्र भाग 2 खण्ड 3 पृष्ठ 451 द्वारा। अध्याय 4 दादरा और नागर हवेली संघ राज्यक्षेत्र में, 1 अगस्त, 1968 से प्रवृत्त हुआ। देखिए अधिसूचना सं० ए०डी०एम० / लो 117 (74) दिनांक 20-7-1968 भारत के राजपत्र के भाग 3 खण्ड 3 पृष्ठ 128 इस अधिनियम का विस्तार 1963 के विनियमन सं० 6 की धारा 2 और अनुसूची I द्वारा दादरा नागर हवेली पर; 1963 के विनियम 6-7 की धारा 3 और अनुसूची I द्वारा पांडिचेरी पर, 1963 के विनियम सं० 11 की धारा 3 और अनुसूची द्वारा गोवा दमन और दीव पर, और 1963 के विनियमन सं० 8 की धारा 3 और अनुसूची द्वारा लक्षदीव, मिनिकाय और अंडमान दीव पर किया गया।
2. 1972 के अधिनियम सं० 19 की धारा 2 द्वारा जोड़ा गया।
3. 1964 के अधिनियम सं० 13 की धारा 2 द्वारा (15-9-1964 से) अन्तःस्थापित।

¹[(कक) “बोर्ड” से अभिप्रेत है—

- (i) (सिद्ध सहित) आयुर्वेदिक या यूनानी औषधि के सम्बन्ध में धारा 33ग के अधीन गठित आयुर्वेदिक और यूनानी औषधि तकनीकी सलाहकार बोर्ड; और
- (ii) किसी अन्य औषधि या प्रसाधन सामग्री के सम्बन्ध में धारा 5 के अधीन गठित औषधि तकनीकी सलाहकार बोर्ड;]

²[³(ककक)] “प्रसाधन सामग्री” से कोई ऐसी चीज अभिप्रेत है जो साफ करने, सुन्दर बनाने, आकर्षकता बढ़ाने, या छवि परिवर्तित करने के लिए मानव शरीर या उसके किसी भाग में मलने, उड़ेलने, छिड़कने, फहारने, या समाविष्ट करने या अन्यथा प्रयुक्त करने के लिए आशयित है तथा प्रसाधन सामग्री के संघटक के रूप में प्रयोग करने के लिए आशयित कोई चीज इसके अन्तर्गत है किन्तु साबुन इसके अन्तर्गत नहीं है;]

⁴[(ख) “औषधि” के अन्तर्गत निम्नलिखित हैं,—

- (i) मनुष्यों या पशुओं के आन्तरिक या बाह्य उपयोग के लिए सब औषधियां तथा सब पदार्थ जो मनुष्यों या पशुओं में ⁵[रोग के निधान, उपचार,] शमन या निवारण के लिए या उसमें उपयोग के लिए आशयित हैं ⁶***; और
- (ii) मानव शरीर की संरचना या किसी क्रिया को प्रभावित करने के लिए आशयित या ऐसे ⁷[पीड़क जन्तु] अथवा कीटों के, जो मनुष्यों या पशुओं में रोग पैदा करते हैं; विनाश के लिए प्रयुक्त किए जाने के लिए आशयित (खाद्य से भिन्न) ऐसे पदार्थ जो केन्द्रीय सरकार द्वारा समय-समय पर शासकीय राजपत्र में अधिसूचना द्वारा विनिर्दिष्ट किए जाएं;]

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1. (15-9-1964 से) मूल खण्ड (क) खण्ड (कक) के रूप में पुनराक्षरित और यथोक्त की धारा 2 द्वारा प्रतिस्थापित ।
 2. 1962 के अधिनियम सं० 21 की धारा 4 द्वारा खण्ड (कक) के रूप में (27-7-1964) अंतःस्थापित ।
 3. 1964 के अधिनियम सं० 13 की धारा 2 द्वारा 12-9-1964 से पुनः अक्षरांकित ।
 4. 1955 के अधिनियम सं० 11 की धारा 2 द्वारा खण्ड (ख) के रूप में प्रतिस्थापित ।
 5. 1960 के अधिनियम सं० 35 धारा 2 द्वारा “उपचार में” शब्दों के स्थान पर 16-3-1961 से प्रतिस्थापित ।
 6. 1964 के अधिनियम सं० 13 की धारा 2 द्वारा 15-9-1964 से कुछ शब्दों का लोप
 7. “पीड़क जन्तु” शब्दों के स्थान पर यथोक्त की धारा 2 द्वारा (15-9-1964 से) प्रतिस्थापित ।

1[(ग) "सरकारी विश्लेषक" से अभिप्रेत है; —

- (i) (सिद्ध सहित) आयुर्वेदिक या यूनानी औषधि के सम्बन्ध में धारा 83च के अधीन केन्द्रीय सरकार या राज्य सरकार द्वारा नियुक्त सरकारी विश्लेषक; और
- (ii) किसी अन्य औषधि या प्रसाधन सामग्री के सम्बन्ध में धारा 20 के अधीन केन्द्रीय सरकार या राज्य सरकार द्वारा नियुक्त सरकारी विश्लेषक;]

2[(ङ) निरीक्षक से अभिप्रेत है—

- (i) (सिद्ध सहित) आयुर्वेदिक या यूनानी औषधि के सम्बन्ध में, धारा 83छ के अधीन केन्द्रीय सरकार या राज्य सरकार द्वारा नियुक्त निरीक्षक; और
- (ii) किसी अन्य औषधि या प्रसाधन सामग्री के सम्बन्ध में धारा 21 के अधीन केन्द्रीय सरकार या राज्य सरकार द्वारा नियुक्त निरीक्षक;]

3[⁴(च)] किसी औषधि ⁵[या प्रसाधन सामग्री] के सम्बन्ध में "विनिर्माण" के अन्तर्गत किसी औषधि ⁵[या प्रसाधन सामग्री] को उसके विक्रय और वितरण की दृष्टि से निर्मित करने, परिवर्तित करने, अलंकृत करने, तैयार करने, पैक करने, उस पर लेबल लगाने, उसे तोड़ने या अन्यथा व्यवहृत अथवा अनुकूलित करने के लिए कोई प्रक्रिया या प्रक्रिया का भाग भी है किन्तु फुटकर कारबार के मामूली अनुक्रम में किसी औषधि की मिश्रता या उसका नुस्खा बनाना अथवा ⁶[किसी औषधि या प्रसाधन सामग्री को पैक करना] इसके अन्तर्गत नहीं है तथा "विनिर्मित करने" का अर्थ तदनुकूल किया जाएगा;]

7[(ठ)] अपने व्याकरणिक रूपभेदों और सजातीय पदों सहित "आयात करने" से ⁸(भारत) में लाना अभिप्रेत है;

9[[(ज)] "पेटेंट या साम्पतिक औषधि" से ऐसी औषधि अभिप्रेत है जो मनुष्यों या पशुओं के आन्तरिक या बाह्य उपयोग के लिए तैयार रूप में प्रस्तुत उपचार

1. खण्ड (ग) के स्थान पर यथोक्त की धारा 2 द्वारा (15-9-1964 से) प्रतिस्थापित ।
2. 1964 के अधिनियम सं० 13 की धारा 2 द्वारा खण्ड (इ) (15-9-1954 से) प्रतिस्थापित ।
3. 1955 के अधिनियम सं० 2 द्वारा खण्ड (खख) प्रतिस्थापित ।
4. 1960 के अधिनियम सं० 35 की धारा 2 द्वारा खण्ड (खखख) को खण्ड (च) के रूप में पुनः अक्षरांकित किया गया ।
5. 1962 के अधिनियम 4 द्वारा (27-7-1964 से) अंतःस्थापित ।
6. "या किसी औषधि को पैक करने" शब्दों का यथोक्त की धारा 4 द्वारा प्रतिस्थापित ।
7. 1960 के अधिनियम सं० 35 की धारा 2 द्वारा (ग), (घ) और (ङ) खण्डों को क्रमशः (छ), (ज) और (झ) खण्डों के रूप में (16-3-1961 से) पुनराक्षरित ।
8. 1951 के अधिनियम सं० 3 की धारा 3 अनुमूची द्वारा "राज्यों" शब्द प्रतिस्थापित ।
9. 1964 के अधिनियम सं० 13 की धारा 2 द्वारा खण्ड (ज) (15-9-1964 से) प्रतिस्थापित ।

या नस्खा है और जो तत्समय भारतीय औषध कोष के या इस निमित्त केन्द्रीय सरकार द्वारा बोर्ड से परामर्श करके प्राधिकृत किसी अन्य औषध कोष के संस्करण के अन्तर्गत नहीं है ;]

¹[²(अ)] “विहित” से इस अधिनियम के अधीन बनाए गए नियमों द्वारा विहित अभिप्रेत है;]

³[3क * * * * *

जम्मू कश्मीर राज्य में अप्रवृत्त किसी विधि या अविद्यमान किसी कृत्यकारी के प्रति निर्देशों का अर्थान्वयन : ⁴ “[3क. जम्मू-कश्मीर राज्य में अप्रवृत्त किसी विधि या अविद्यमान किसी कृत्यकारी के प्रति, इस अधिनियम में किसी निर्देश का, उस राज्य के सम्बन्ध में, यह अर्थ लगाया जाएगा कि वह उस राज्य में प्रवृत्त तत्समान विधि या विद्यमान तत्समान कृत्यकारी के प्रति निर्देश हैं।”]

4. विपैले पदार्थों के बारे में उपधारणा : अध्याय 3 या अध्याय 4 ⁵[या अध्याय 4क] के अधीन बनाए गए नियम द्वारा विपैले पदार्थ के रूप में विनिर्दिष्ट कोई पदार्थ यथास्थिति अध्याय 3 या अध्याय 4 ⁵[या अध्याय 4क] के प्रयोजनों के लिए विपैला पदार्थ समझा जाएगा ।

1. 1955 के अधिनियम सं० 11 की धारा 2 द्वारा मूल खंड (ड) प्रतिस्थापित ।
2. 1960 के अधिनियम सं० 35 की धारा 2 द्वारा (ग), (घ) और (ङ) खण्डों को क्रमशः (छ), (ज) और (झ) खण्डों के रूप में (16-3-1961 से) पुनराक्षरित ।
3. विधि अनुकूलोकरण आदेश, 1950 द्वारा अन्तःस्थापित खण्ड (च) का 1951 के अधिनियम सं० 3 की धारा 3 और अनुसूची द्वारा लोप ।
4. 1972 के अधिनियम सं० 19 की धारा 4 द्वारा अन्तःस्थापित ।
5. 1964 के अधिनियम सं० 13 की धारा 3 द्वारा (15-9-1964 से) अन्तःस्थापित ।

औषधि तकनीकी सलाहकार बोर्ड, केन्द्रीय औषधि द्रव्य

प्रयोगशाला और औषधि परामर्श समिति

5. औषधि तकनीकी सलाहकार बोर्ड :—(1) केन्द्रीय सरकार इस अधिनियम के प्रशासन से पैदा होने वाले तकनीकी मामलों पर केन्द्रीय सरकार और राज्य सरकारों को परामर्श देने के लिए और इस अधिनियम द्वारा उसे सौंपे गए अन्य कृत्यों को करने के लिए यथाशक्य शीघ्रता से (औषधि तकनीकी सलाहकार बोर्ड कहलाने वाला) एक बोर्ड गठित करेगी।

¹[(2) बोर्ड निम्नलिखित सदस्यों से मिलकर बनेगा, अर्थात्—

- (i) स्वास्थ्य सेवा-महानिदेशक, पदेन, जो अध्यक्ष होगा ;
- (ii) औषधि नियंत्रक, भारत, पदेन ;
- (iii) केन्द्रीय औषधि प्रयोगशाला निदेशक, कलकत्ता, पदेन ;
- (iv) केन्द्रीय अनुसंधान संस्थान निदेशक, कसौली, पदेन ;
- (v) भारतीय पशु-चिकित्सा अनुसंधान संस्थान निदेशक, इज्जत नगर, पदेन ;
- (vi) भारतीय चिकित्सा परिषद् का अध्यक्ष, पदेन ;
- (vii) भारतीय फार्मसी परिषद् का अध्यक्ष, पदेन ;
- (viii) केन्द्रीय औषधि अनुसंधान संस्थान, निदेशक, लखनऊ, पदेन ;
- (ix) ऐसे व्यक्तियों में से जो राज्यों में औषधियों के नियंत्रण के भार-साधक हैं ; केन्द्रीय सरकार द्वारा नामनिर्देशित किए जाने वाले दो व्यक्ति ;
- (x) किसी भारतीय विश्वविद्यालय या उससे सम्बद्ध किसी कालेज के कर्मचारिवृन्द में फार्मसी या भेषजिक रसायन या भेषज-अभिज्ञान के शिक्षकों में से भारतीय फार्मसी परिषद् की कार्यपालिका समिति द्वारा निर्वाचित किया जाने वाला एक व्यक्ति ;
- (xi) किसी भारतीय विश्वविद्यालय या उससे सम्बद्ध किसी कालेज के कर्मचारिवृन्द में औषधि या चिकित्सा शास्त्र के शिक्षकों में से भारतीय चिकित्सा परिषद् की कार्यपालिका समिति द्वारा निर्वाचित किया जाने वाला एक व्यक्ति ;

1. 1964 के अधिनियम सं० 13 की धारा 4 द्वारा उपधारा(2) के स्थान पर (15-9-1977) से प्रतिस्थापित।

- (xii) भेषजिक उद्योग से केन्द्रीय सरकार द्वारा नामनिर्देशित किया जाने वाला एक व्यक्ति;
- (xiii) भारतीय चिकित्सा अनुसंधान परिषद् के शासी निकाय द्वारा निर्वाचित किया जाने वाला एक भेषज गुण विज्ञानी ;
- (xiv) भारतीय चिकित्सा संगम की केन्द्रीय परिषद् द्वारा निर्वाचित किया जाने वाला एक व्यक्ति ;
- (xv) भारतीय भेषजिक संगम की परिषद् द्वारा निर्वाचित किया जाने वाला एक व्यक्ति ;
- (xvi) इस अधिनियम के अधीन सरकारी विश्लेषक वा पद धारण करने वाले दो व्यक्ति जो केन्द्रीय सरकार द्वारा नामनिर्देशित किए जाएंगे ।]

(3) बोर्ड के नामनिर्देशित और निर्वाचित सदस्य अपना पद तीन वर्ष तक धारण करेंगे, किन्तु पुनर्नामनिर्देशन और पुनर्निर्वाचन के लिए पात्र होंगे ;

¹[परन्तु उपधारा (2) के खण्ड (ix) या खण्ड (x) या खण्ड (xi) या खण्ड (xvi) के अधीन यथास्थिति नामनिर्देशित या निर्वाचित व्यक्ति तब तक पद धारण करता रहेगा जब तक वह उस पद की नियुक्ति धारण किए रहता है जिस के आधार पर वह बोर्ड में नामनिर्देशित या निर्वाचित किया गया था ।]

(4) केन्द्रीय सरकार के पूर्व अनुमोदन के अधीन रहते हुए बोर्ड, अपनी गणपूर्ति नियत करने वाली और अपनी प्रक्रिया और अपने द्वारा किए जाने वाले सब काम-काज का संचालन विनियमित करने वाली उपविधियां बना सकेगा ।

(5) बोर्ड उपसमितियां गठित कर सकेगा और ऐसी उपसमितियों में तीन वर्ष से अधिक न होने वाली ऐसी कालावधियों के लिए, जैसी वह विनिश्चित करे, या विनिश्चित मामलों के विचारार्थ अस्थायी रूप में, ऐसे व्यक्तियों को नियुक्त कर सकेगा जो बोर्ड के सदस्य नहीं हैं ।

(6) बोर्ड में किसी रिक्तता के होते हुए भी उसके कृत्य किए जा सकेंगे ।

(7) केन्द्रीय सरकार किसी व्यक्ति को बोर्ड का सचिव नियुक्त करेगी और बोर्ड के लिए ऐसे लिपिकीय और अन्य कर्मचारीवृन्द उपलब्ध करेगी जैसे केन्द्रीय सरकार आवश्यक समझती है ।

6. केन्द्रीय औषधि प्रयोगशाला : (1) केन्द्रीय सरकार अपने द्वारा नियुक्त किए जाने वाले निदेशक के नियवणाधीन एक केन्द्रीय औषधि प्रयोगशाला उन कृत्यों को करने के लिए यथाशक्य शीघ्र स्थापित करेगी जो उसे इस अधिनियम द्वारा या इस अध्याय के अधीन बनाए गए किन्हीं नियमों द्वारा सौंपे गए हैं :

परन्तु यदि केन्द्रीय सरकार ऐसा विहित करे तो किसी औषधि या औषधियों के वर्ग ²[या प्रसाधन सामग्री या प्रसाधन सामग्रियों के वर्ग] के लिए केन्द्रीय औषधि प्रयोगशाला के कृत्य

1. 1964 के अधिनियम सं० 13 की धारा 4 द्वारा परन्तुक के स्थान पर (15-9-1964 से) प्रतिस्थापित ।

2. 1962 के अधिनियम सं० 21 की धारा 5 (27-7-1964 से) अंतःस्थापित ।

केन्द्रीय अनुसंधान संस्थान कसौ नो में वा किसी अन्य विहित प्रयोगशाला में किए जाएंगे और ऐसे प्रौद्योगिकी या प्रौद्योगिकियों के वर्ग या ¹[ऐसे प्रसाधन सामग्रियों या प्रसाधन सामग्रियों के वर्ग] के बारे में केन्द्रीय औषधि प्रयोगशाला निदेशक के कृत्य यथास्थिति उस संस्था के या उस प्रयोगशाला के निदेशक द्वारा किए जाएंगे।

(2) केन्द्रीय सरकार बोर्ड से परामर्श करने के पश्चात् निम्नलिखित को विहित करने वाले नियम बना सकेगी—

(क) केन्द्रीय औषधि प्रयोगशाला के कृत्य,

²[* * * * *]

(ख) विरलेक्षण या परख के लिए औषधियों ¹[या प्रसाधन सामग्रियों] के नमूनों को उक्त प्रयोगशाला को ³[अध्याय 4 या अध्याय 4क के अधीन] भेजने की प्रक्रिया प्रयोगशाला की तत्सम्बन्धी रिपोर्टों के प्ररूप और ऐसी रिपोर्टों के लिए देय फीस,

(ङ) ऐसी प्रत्येक बातें जो उक्त प्रयोगशाला को अपने कृत्यों को करने के लिए योग्य बनाने के लिए आवश्यक या समीचीन हों,

(च) उपधारा (1) के परन्तुक के प्रयोजनों के लिए विहित किए जाने के लिए आवश्यक विषय।

7. औषधि परामर्श समिति : (1) केन्द्रीय सरकार इस अधिनियम के प्रशासन में ⁴[मारा] में एतद्वारा लाने को प्रवृत्ति रखने वाली किसी बात पर, केन्द्रीय सरकार, राज्य सरकारों और औषधि तत्सम्बन्धी सलाहकार बोर्ड को सलाह देने के लिए “औषधि परामर्श समिति” कहाने वाली एक सलाहकार समिति गठित कर सकेगी।

(2) औषधि परामर्श समिति केन्द्रीय सरकार द्वारा नामनिर्देशित किए जाने वाले उस सरकार के दो प्रतिनिधियों से और संबंधित राज्य सरकारों द्वारा नामनिर्देशित किए जाने वाले प्रत्येक राज्य सरकार के एक-एक प्रतिनिधि से मिलकर गठित होगी।

(3) औषधि परामर्श समिति केन्द्रीय सरकार द्वारा, अशेषित किए जाने पर अधिविष्ट होगी और उसे अपनी प्रक्रिया स्वयं विनियमित करने की शक्ति होगी।

(सिद्ध सहित) आयुर्वेदिक या यूनानी औषधियों को धारा 5 और 7 का लागू न होना : ⁵[7क. धारा 5 और 7 में अन्तर्विष्ट कोई बात (सिद्ध सहित) आयुर्वेदिक या यूनानी औषधियों को लागू नहीं होंगी।]

1. 1962 के अधिनियम सं० 21 की धारा 5 (27-7-1964 से) अन्तःस्थापित।
2. 1955 के अधिनियम सं० 11 की धारा 4 द्वारा (ख) और (ग) खण्डों का लोप।
3. 1964 के अधिनियम सं० 13 की धारा 5 द्वारा “अध्याय 4 के अधीन” के स्थान पर (15-9-1964) प्रतिस्थापित।
4. 1951 के अधिनियम सं० 3 की धारा 3 और अनुसूची द्वारा “या राज्यों” के स्थान पर प्रतिस्थापित।
5. 1964 के अधिनियम सं० 13 की धारा 6 द्वारा (15-9-1964 से) अन्तःस्थापित।

औषधियों का आयात

8. क्वालिटी के मानक :¹ [(1) इस अध्याय के प्रयोजनों के लिए "मानक क्वालिटी" पद से अभिप्रेत है—

- (क) औषधि के सम्बन्ध में यह कि औषधि² [द्वितीय अनुसूची] में उपवर्णित मानक का अनुवर्तन करती है, और
- (ख) प्रसाधन सामग्री के सम्बन्ध में यह कि प्रसाधन सामग्री ऐसे मानक का अनुवर्तन करती है जैसा विहित किया जाए ।]

(2) केन्द्रीय सरकार, इस अध्याय के प्रयोजनों के लिए² [द्वितीय अनुसूची] का परिवर्धन या अन्यथा संशोधन, बोर्ड से परामर्श करने के पश्चात् और वैसा करने के अपने आशय की तीन मास से अन्यून को सूचना शासकीय राजपत्र में अधिमूचना द्वारा देकर, वैसी ही अधिमूचना द्वारा कर सकेगी और तब² [द्वितीय अनुसूची] तदनुकूल संशोधित समझी जाएगी ।

9. मिथ्या छाप वाली औषधियां : इस अध्याय के प्रयोजनों के लिए किसी औषधि को मिथ्या छाप वाली समझा जाएगा—

- (क) यदि वह किसी अन्य औषधि की नकल है, उसके बदले में है, या उससे इस प्रकार मिनती जुलती है कि धोखा हो जाय या उस पर या उसके लेबल अथवा पात्र पर अन्य औषधि का नाम है जब तक कि वह साफ और संलक्ष्य रूप से इस प्रकार चिह्नित न हो कि उसका वास्तविक स्वरूप और ऐसी अन्य औषधि के साथ अनन्यता का अभाव प्रकट हो जाए; या
- (ख) यदि वह ऐसे स्थान और देश की उत्पत्ति होनी तात्पर्यित है जिसकी उत्पत्ति वह वास्तव में नहीं है; या
- (ग) यदि उसका आयात से नाम ऐसे किया जाता है जो किसी अन्य औषधि का नाम है; या
- (घ) यदि वह इस प्रकार रंजित, विनैपित, चूर्णकृत या पालिश की हुई है कि नुकसान छिप जाता है, या यदि वह उससे बेहतर या अधिक चिकित्सीय महत्व की होनी अभिव्यक्त की जाती है जितनी कि वह वास्तव में नहीं है ; या
- (ङ) यदि उस पर लेबल विहिन रोति से नहीं लगाया जाता है ; या
- (च) यदि उसके लेबल या पात्र अथवा उसके साथ किसी चीज पर कोई ऐसा कथन, डिजाइन या युक्ति है जो उस औषधि के लिए कोई मिथ्या दावा करती है अथवा जो किसी विशिष्ट में मिथ्या या भुलावा देने वाली है; या ;

1. 1962 के अधिनियम सं० 21 की धारा 6 द्वारा उपधारा (1) के स्थान पर (27-7-1964 से) प्रतिस्थापित ।

2. 1964 के अधिनियम सं० 13 की धारा 7 द्वारा "अनुसूची" के स्थान पर (15-9-1964 से) प्रतिस्थापित ।

(छ) यदि उसके लेबल या पात्र में उस औषधि का विनिर्माता या उत्पादक होना तात्पर्यित किसी ऐसे व्यष्टि या कम्पनी का नाम है जो व्यष्टि या कम्पनी काल्पनिक है या अस्तित्व में नहीं है।

¹[9क. मिथ्या छाप वाली प्रसाधन सामग्रियां : इस धारा के प्रयोजनों के लिए किसी प्रसाधन सामग्री को मिथ्या छाप वाली समझा जाएगा :—

- (क) यदि वह किसी अन्य प्रसाधन सामग्री की नकल है, उसके बदले में है या उससे इस प्रकार मिलती जुलती है कि धोखा हो जाए ; या
- (ख) यदि वह ऐसे स्थान या देश की उत्पत्ति होनी तात्पर्यित है जिसकी उत्पत्ति वह वास्तव में नहीं है ; या
- (ग) यदि उसमें ऐसा रंग है जो विहित नहीं है ; या
- (घ) यदि उसका आयात ऐसे नाम से किया जाता है जो किसी अन्य प्रसाधन सामग्री का नाम है ; या
- (ङ) यदि उस पर लेबल विहित रीति से नहीं लगाया जाता है ; या
- (च) यदि उसके लेबल या पात्र में उस प्रसाधन सामग्री का विनिर्माता या उत्पादक होना तात्पर्यित किसी ऐसे व्यष्टि या कम्पनी का नाम है जो व्यष्टि या कम्पनी काल्पनिक है या अस्तित्व में नहीं है ; या
- (छ) यदि उसके लेबल या पात्र में कोई ऐसा कथन है जो मिथ्या है या किसी विशिष्ट में भुलावा देने वाला है।]

²[9 ख. अपमिश्रित औषधियां : इस अध्याय के प्रयोजनों के लिए, किसी औषधि को अपमिश्रित समझा जाएगा :—

- (क) यदि वह पूर्णतः या भागतः किसी गन्दे, गलित या विघटित पदार्थ से बनी है ; या
- (ख) यदि वह अस्वच्छ परिस्थितियों में तैयार की गई, पैक की गई या भण्डार में रखी गई है जिससे वह गंदगी से संदूषित हो गई हो या जिससे वह स्वास्थ्य के लिए क्षतिकर हो गई हो ; या
- (ग) यदि उसका पात्र पूर्णतः या भागतः किसी विषैले या हानिकारक पदार्थ से बना हो जो उसकी अर्न्तवस्तुओं को स्वास्थ्य के लिए क्षतिकर बना दे ; या
- (घ) यदि केवल रंजन के प्रयोजनों के लिए उसमें ऐसा रंग है या अन्तर्विष्ट है जो विहित रंग से भिन्न है ; या

1. 1962 के अधिनियम सं० 21 की धारा 7 द्वारा (27-7-1964 से) अन्तः-स्थापित।

2. 1964 के अधिनियम सं० 13 की धारा 8 द्वारा (15-9-1964 से) अन्तः-स्थापित।

(ड) यदि किसी पदार्थ को :—

(i) उसके साथ मिलाया या पैक किया गया हो जिससे उसकी क्वालिटी या सामर्थ्य घट जाए ; या

(ii) पूर्णतः या भागतः उसके बदले में रख दिया गया हो ।

स्पष्टीकरण—खण्ड (क) के प्रयोजनों के लिए किसी औषधि को पूर्णतः या भागतः किसी विघटित पदार्थ से बना केवल इस बात के कारण नहीं समझा जाएगा कि ऐसा विघटित पदार्थ, उस औषधि के लेबल पर विनिर्दिष्ट उस कालावधि के अन्दर, यदि कोई हो, जिसके दौरान उस औषधि का उपयोग किया जाना है उस औषधि के किसी प्राकृतिक विघटन का परिणाम है :

परन्तु तब जब कि ऐसा विघटन उस औषधि के विनिर्माता या उसके आयातकर्ता या ब्योहारी की किसी उपेक्षा के कारण नहीं हुआ है और वह उस औषधि को स्वास्थ्य के लिए क्षतिकर नहीं बनाता है ।]

10 कतिपय औषधियां या प्रसाधन सामग्रियों के आयात का प्रतिषेध : उस ¹[तारीख] से जो केन्द्रीय सरकार द्वारा शासकीय राजपत्र में अधिसूचना द्वारा इस निमित्त नियत की जाए, कोई व्यक्ति निम्नलिखित का आयात नहीं करेगा —

(क) कोई ऐसी औषधि ²[या प्रसाधन सामग्री] जो मानक क्वालिटी की नहीं है ;

³[(ख) कोई मिथ्या छाप वाली औषधि या मिथ्या छाप वाली प्रसाधन सामग्री ;]

⁴[(खख) कोई अपमिश्रित औषधि ;]

(ग) कोई औषधि ²[या प्रसाधन सामग्री] जिसके आयात के लिए अनुज्ञप्ति विहित है, ऐसे अनुज्ञप्ति के अधीन और अनुकूल से अन्यथा ;

1. 1 अप्रैल, 1947 (क), (ख), (ग) और (ड़) और (च) खण्डों के लिए 1 अप्रैल, 1947 और खण्ड (घ) के लिए 1 अप्रैल, 1949 देखिए ।

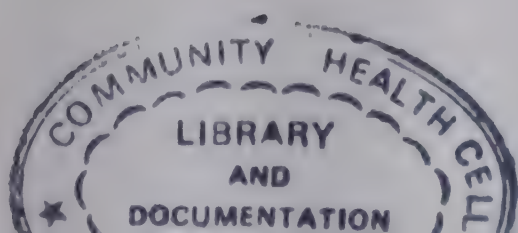
अधिसूचना सं० 18-12/46-डी०-1, दिनांक 11 फरवरी, 1947, 1947 के भारत के राजपत्र के भाग 1 पृष्ठ 189 जो अधिसूचना सं० एफ० -1-2/48-डी० (i) दिनांक 19-9-1948 द्वारा यथा संशोधित हुआ ।

कानूनो नियम आदेश अधिसूचना सं० 666 दिनांक 20-3-1953, 1953 के भारत के राजपत्र भाग 2, खण्ड 3, पृष्ठ 451 से हिमाचल प्रदेश, बिलासपुर, कच्छ, भोगल, त्रिपुरा, विन्ध्य प्रदेश और मणिपुर राज्यों के लिए 1 अप्रैल, 1953 ।

2. 1962 के अधिनियम सं० 21 की धारा 8 द्वारा (27-7-1964 से) अन्तः-स्थापित ।

3. यथोक्त की धारा 8 द्वारा खंड (ख) के स्थान पर (27-7-1964 से) प्रतिस्थापित ।

4. 1964 के अधिनियम सं० 13 की धारा 9 द्वारा (15-9-1964 से) अन्तः-स्थापित ।



¹[(घ) कोई पेटेन्ट या साम्पत्तिक औषधि, जब तक कि उसके लेबल या पात्र पर विहित रीति से, उसमें अन्तर्विष्ट संघटकों का सही फारमूला या सूची चिकित्सा वृत्ति के सदस्यों को आसानी से समझ में आ जाने वाली रीति से संप्रदर्शित न हो ;]

(ङ) कोई औषधि जो उसके साथ के किसी कथन, परिकल्पना या आकृति से या किसी अन्य साधन से, किसी ऐसे रोग या व्याधि का ठीक करना या उसका शमन करना अथवा कोई ऐसा अन्य प्रभाव जैसा विहित किया जाए रखना तात्पर्यित करती है या उसका दावा करती है ;

²[(ङङ) कोई प्रसाधन सामग्री जिसमें ऐसे संघटक अन्तर्विष्ट हों जो उसे ऐसे निदेशों के अधीन, जो उपदर्शित किए गए हों या जिनकी सिफारिश की गई हो, प्रयोग के लिए असुरक्षित या अपहानिकर बनाएं ;]

(च) कोई ऐसी औषधि ³[या प्रसाधन सामग्री] जिसका आयात इस अध्याय के अधीन बनाए गए नियम द्वारा प्रतिषिद्ध है ;

परन्तु इस धारा की कोई बात परीक्षा, परख या विश्लेषण के प्रयोजन के लिए या व्यक्तिगत उपयोग के लिए किसी औषधि के विहित 'शर्तों' के अध्यधीन थोड़े परिमाण में आयात को लागू नहीं होगी :

परन्तु यह और कि केन्द्रीय सरकार बोर्ड के साथ परामर्श करने के पश्चात् शासकीय राजपत्र में अधिसूचना द्वारा, उस अधिसूचना में विनिर्दिष्ट किन्हीं शर्तों के अध्यधीन, मानक क्वालिटी की न होने वाली किसी औषधि या औषधियों के वर्ग के आयात की अनुज्ञा दे सकेगी ।

स्पष्टीकरण—खण्ड (घ) में वर्णित संघटकों के फारमूला या सूची को उस खण्ड का ठीक और पर्याप्त अनुपालन समझा जाएगा यदि संघटकों का पूर्ण और ब्यौरेवार नुस्खा प्रकट किए बिना वह सही तौर से उन सब शक्त और विषले पदार्थों को, जो उसमें अन्तर्विष्ट हों, औषधि की रचना के ठीक-ठीक विवरण सहित, उपदर्शित करती है ।

11. सागर-सीमा शुल्क से सम्बद्ध विधि का लागू होना और सीमा शुल्क अधिकारियों की शक्तियाः (1) सागर-सीमा शुल्कों से और ऐसे मालों से, जिनका आयात सागर ⁴[सीमाशुल्क अधिनियम, 1878] (1878 का 8) की धारा 18 द्वारा प्रतिषिद्ध है, सम्बद्ध तत्समय प्रवृत्त विधि इस अधिनियम की धारा 13 के उपबन्धों के अधीन रहते हुए उन औषधियों ⁵[और प्रसाधन सामग्रियों] के बारे में लागू होगी, जिनका आयात इस अध्याय के अधीन प्रतिषिद्ध किया

1. 1955 के अधिनियम सं० 11 की धारा 5 द्वारा खंड (च) के स्थान पर प्रतिस्थापित ।

2. 1962 के अधिनियम सं० 21 द्वारा (27-7-1964 से) अंतःस्थापित ।

3. 1962 के अधिनियम सं० 21 द्वारा (24-4-1964 से) अंतःस्थापित ।

4. अब सीमा शुल्क अधिनियम, 1962 देखिए ।

5. 1962 के अधिनियम सं० 21 की धारा 9 द्वारा (27-7-1964 से) अन्तःस्थापित ।

गया है, और सीमा-शुल्क अधिकारियों और ऐसे अधिकारियों की, जो कि तद्द्वारा सीमा-शुल्क कलक्टर और सीमा-शुल्क के अन्य अधिकारियों पर अधिरोपित कर्तव्यों के पालन के लिए उस अधिनियम के अधीन सशक्त हैं, शक्तियाँ ऐसी औषधियों ¹[और प्रसाधन सामग्रियों] के बारे में वही होंगी, जैसी पूर्वोक्त जैसे मालों के बारे में उनकी तत्समय हैं।

²[(2) उपधारा (1) के उपबन्धों पर प्रतिकूल प्रभाव डाले बिना सीमा-शुल्क कलक्टर या केन्द्रीय सरकार द्वारा इस निमित्त प्राधिकृत सरकार का कोई अधिकारी ऐसे किसी आयात किए गए पैकेज को निरुद्ध कर सकेगा, जिसके बारे में उसे संदेह है कि उसके भीतर कोई ऐसी औषधि ¹[या प्रसाधन सामग्री] अन्तर्विष्ट है, जिसका आयात इस अध्याय के अधीन प्रतिषिद्ध है, और ऐसे निरोध की रिपोर्ट औषधि नियंत्रक, भारत को तत्काल करेगा, और, यदि आवश्यक हो, तो वह पैकेज या उसमें पाई गई किसी सन्देहजनक औषधि ¹[या प्रसाधन सामग्री] का नमूना केन्द्रीय औषधि प्रयोगशाला को भेजेगा।]

12. नियम बनाने की केन्द्रीय सरकार की शक्ति— (1) केन्द्रीय सरकार बोर्ड के साथ परामर्श करने के पश्चात् और शासकीय राजपत्र में अधिसूचना द्वारा पूर्व प्रकाशन के पश्चात् इस अध्याय के उपबन्धों को प्रभावी करने के प्रयोजन के लिए नियम बना सकेगी :

³[परन्तु यदि केन्द्रीय सरकार की यह राय हो कि ऐसी परिस्थितियाँ पैदा हो गई हैं, जिन से आवश्यक हो गया है कि बोर्ड के साथ ऐसे परामर्श के बिना नियम बना लिए जाएं तो बोर्ड के साथ परामर्श अभिमोचित किया जा सकेगा, किन्तु ऐसी दिशा में नियम बना लेने के छह मास के अन्दर बोर्ड से परामर्श किया जाएगा और केन्द्रीय सरकार किन्हीं भी ऐसे सुझावों पर, जो बोर्ड उक्त नियमों के संशोधन के सम्बन्ध में दे, विचार करेगी।]

(2) पूर्वगामी शक्ति की व्यापकता पर प्रतिकूल प्रभाव डाले बिना ऐसे नियम :—

(क) उन औषधियों या औषधियों के वर्ग ⁴[या प्रसाधन सामग्रियों या प्रसाधन सामग्रियों के वर्ग] को, जिनके आयात करने के लिए अनुज्ञप्ति अपेक्षित है, विनिर्दिष्ट कर सकेंगे और ऐसी अनुज्ञप्तियों के प्ररूप और शत, उनको देने के लिए सशक्त प्राधिकारी और उनके लिए देय फीसों विहित कर सकेंगे;

(ख) यह अवधारण करने में की जाने वाली परख या विश्लेषण के ढंग विहित कर सकेंगे कि क्या कोई औषधि ⁴[या प्रसाधन सामग्री] मानक क्वालिटी की है ;

(ग) जीवी और अंग-धात्विक सम्मिश्रणों के सम्बन्ध में मानकीकरण की इकाइयाँ या ढंग विहित कर सकेंगे;

1. 1962 के अधिनियम सं० 21 की धारा 9 द्वारा (27-7-64) से अन्तःस्थापित।

2. 1955 के अधिनियम सं० 17 की धारा 6 द्वारा उपधारा (2) के स्थान पर प्रतिस्थापित।

3. 1955 के अधिनियम सं० 11 की धारा 7 द्वारा अन्तःस्थापित।

4. 1962 के अधिनियम सं० 21 की धारा 10 द्वारा (27-7-1964 से) अन्तःस्थापित।

¹[(ग) धारा 9 ख के खण्ड (घ) के अधीन उस रंग या उन रंगों को विहित कर सकेंगे जो रंजन के प्रयोजनों के लिए किसी ओषधि में हों या या अन्तर्विष्ट हो सकेंगे ;]

(घ) उन रोगों और व्याधियों को जिनका ²[निवारण, ठीक या शमन करना] तात्पर्यित या उसका दावा कोई आयात ओषधि नहीं करती और ऐसे अन्य प्रभावों को जिनका रखना तात्पर्यित या उसका दावा ऐसी ओषधि नहीं करती, विनिर्दिष्ट कर सकेंगे ;

(ङ) एपो शर्तों को विहित कर सकेंगे, जिनके अधीन रहने हुए उन ओषधियों का, जिनका आयात इस अध्याय के अधीन अन्यथा प्रतिषिद्ध है, परीक्षा, परख या विश्लेषण के लिए या व्यक्तिगत उपयोग के लिए थोड़े परिमाण में आयात किया जा सकेगा ;

(च) उन स्थानों को विहित कर सकेंगे जिनमें औषधियां ³[या प्रसाधन सामग्रियां] आयात की जा सकेंगी, और किसी अन्य स्थान में उनका आयात प्रतिषिद्ध कर सकेंगे ;

(छ) यह अधिनियम कर सकेंगे कि किसी विनिर्दिष्ट आयात औषधि या ऐसी औषधियों के वर्ग के विनिर्माण की तारीख और शक्तता के अवमान की तारीख उनके लेबल या अनुवर्णक पर स्पष्टतः और सही रूप में कथित की जाए और उक्त औषधि या औषधियों के वर्ग का उसके विनिर्माण की तारीख से किसी विनिर्दिष्ट कारावधि के प्रवृत्तान के पश्चात् आयात प्रतिषिद्ध कर सकेंगे ;

(ज) औषधियों ³[या प्रसाधन सामग्रियों] के नमूनों का आयातकर्ताओं द्वारा केन्द्रीय ओषधि प्रयोगशाला द्वारा परीक्षा, परख या विश्लेषण के लिए भेजा जाना या प्राप्त किया जाना विनियमित कर सकेंगे और ऐसी परीक्षा, परख या विश्लेषण के लिए देय फीसों को, यदि कोई हों, विहित कर सकेंगे ;

(झ) उन औषधियों ³[या प्रसाधन सामग्रियों] की, जिनका आयात चाहा गया है, क्वालिटी का, चाहे साथ की दस्तावेजों से या अन्यथा दिया जाने वाला साक्ष्य, ऐसे साक्ष्य के बारे में सीमा-शुल्क के अधिकारियों द्वारा की जाने वाली कार्रवाई की प्रक्रिया, और प्रवेश लम्बित रहने तक निरुद्ध ओषधियों ³[या प्रसाधन सामग्रियों] के आयात के स्थानों पर भंडारकरण की रीति, विहित कर सकेंगे ;

1. 1964 के अधिनियम सं० 13 की धारा द्वारा (15-9-1964 से) अन्तःस्थापित ।

2. 1955 के अधिनियम सं० 11 की धारा 7 "द्वारा निरोग या शमन करने" के स्थान पर प्रतिस्थापित ।

3. 1962 के अधिनियम सं० 21 की धारा 10 द्वारा (27-7-1964) से अन्तःस्थापित ।

- (जा) उन औषधियों ¹[या प्रसाधन सामग्रियों] को, जो ²[भारत] में हों कर पार जाने के लिए और भारत से निर्यात के प्रयोजन के लिए ही आयात की गई हैं, इस अध्याय के और तदधीन बनाए गए नियमों के सब या किन्हीं उपबंधों से सशर्त या अन्यथा छूट देने के लिए उपबन्ध कर सकेंगे ;
- (ट) आयात औषधियों ¹[या प्रसाधन सामग्रियों] को बोतलों, पैकेजों या अन्य आधानों में पैक करने में पालनीय शर्तें विहित कर सकेंगे ;
- (ठ) पैकेजों में विक्रय के लिए आयात की गई औषधियों ¹[या प्रसाधन सामग्रियों] पर लेबल लगाने का तरीका विनियमित कर सकेंगे, और वे बातें विहित कर सकेंगे जो ऐसे लेबलों में हो सकेंगी या नहीं हो सकेंगी ।
- (ड) ऐसे किसी विप्ले पदार्थ के अधिकतम अनुपात को विहित कर सकेंगे, जो किसी आयात औषधि में मिलाया जा सकेगा या अन्तर्विष्ट किया जा सकेगा, ऐसी किसी औषधि के आयात को प्रतिषिद्ध कर सकेंगे जिसमें वह अनुपात अधिक हो गया है, और उन पदार्थों को विनिर्दिष्ट कर सकेंगे, जो इस अध्याय और तदधीन बनाए गए नियमों के प्रयोजनार्थ विप्ले समझे जाएंगे ;
- (ढ) यह अपेक्षित कर सकेंगे कि किसी विनिर्दिष्ट औषधि का स्वीकृत वैज्ञानिक नाम ऐसी किसी आयात की हुई पेटेन्ट या साम्प्रतिक औषधि के लेबल या आवेष्टक पर, जिसमें ऐसी औषधि अन्तर्विष्ट है, विहित रीति में सम्प्रदर्शित किया जाए ;
- (ण) इस अध्याय या तदधीन बनाए गए नियमों के सब का किन्हीं उपबंधों के किसी विनिर्दिष्ट औषधि या औषधियों के वर्ग ¹[या प्रसाधन सामग्री या प्रसाधन सामग्रियों के वर्ग] को सशर्त या अन्यथा छूट देने के लिए उपबन्ध कर सकेंगे ।

13 अपराध—(1) जो कोई इस अध्याय के या तदधीन बनाए गए किसी नियम के उपबंधों में से किसी का उल्लंघन करेगा वह किसी ऐसी शास्ति के अतिरिक्त, जिसका वह धारा 11 के उपबंध के अधीन दायित्वधीन हो, कारावास से, जो एक वर्ष तक का हो सकेगा, या जुर्माने से, जो पांच सौ रुपए तक का हो सकेगा, अथवा दोनों से दंडनीय होगा ।

(2) जो कोई उपधारा (1) के अधीन सिद्धदोष हो जाने पर उस उपधारा के अधीन पुनः सिद्धदोष ठहराया जाएगा वह उपर्युक्त जैसी किसी शास्ति के अतिरिक्त कारावास से, जो दो वर्ष तक हो सकेगा, या जुर्माने से, जो एक हजार रुपए तक का हो सकेगा, अथवा दोनों से दण्डनीय होगा ।

1. 1962 के अधिनियम सं० 21 की धारा 10 द्वारा (27-7-1964) से अन्तस्थापित ।

2. 1951 के अधिनियम सं० 3 की धारा 3 द्वारा राज्यों के स्थान पर प्रतिस्थापित ।

14. अधिहरण : जहां धारा 13 के अधीन दंडनीय कोई अपराध किया गया है, वहां उस औषधि ¹[या प्रसाधन सामग्री] का वह परेषित परिमाण जिसके बारे में अपराध किया गया है, अधिहरणीय होगा।

15. अधिकारिता : प्रेसिडेंसी मजिस्ट्रेट या प्रथम वर्ग के मजिस्ट्रेट से अवर कोई न्यायालय धारा 13 के अधीन दंडनीय अपराध का विचारण नहीं करेगा।

1. यथोक्त की धारा 11 द्वारा (27-7-1964 से) अन्तःस्थापित।

अध्याय 4

औषधियों का विनिर्माण, विक्रय और वितरण

16. ¹[क्वालिटी के मानक—(1) इस अध्याय के प्रयोजनों के लिए “मानक क्वालिटी” पद से अभिप्रेत है :—

(क) औषधि के सम्बन्ध में यह कि औषधि द्वितीय अनुसूची में उपवर्णित मानक का अनुवर्तन करती है, और

(ख) प्रसाधन सामग्री के सम्बन्ध में यह कि प्रसाधन सामग्री ऐसे मानक का अनुवर्तन करती है जैसा विहित किया जाए।]

(2) ²[केन्द्रीय सरकार] इस अध्याय के प्रयोजनों के लिए ³[द्वितीय अनुसूची] का परिवर्धन या अन्यथा संशोधन, बोर्ड से परामर्श करने के पश्चात् और ऐसा करने के अपने आशय की तीन मास से अन्यून की सूचना शासकीय राजपत्र में अधिसूचना द्वारा देकर, वैसा ही अधिसूचना द्वारा कर सकेगी और तब ³[द्वितीय अनुसूची] तदनुकूल संशोधित समझी जाएगी।

17. मिथ्या छाप वाली औषधियां—इस अध्याय के प्रयोजनों के लिए किसी औषधि को मिथ्या छाप वाली समझा जाएगा —

(क) यदि वह किसी अन्य औषधि की नकल है, उसके बदले में है, या उससे इस प्रकार मिलती जुलती है कि धोखा हो जाए या उस पर या उसके लेबल अथवा आधान पर अन्य औषधि का नाम है जब तक कि वह साफ और संलक्ष्य रूप से इस प्रकार चिह्नित न हो कि उसका वास्तविक स्वरूप और ऐसी अन्य औषधि के साथ अनन्यता का अभाव प्रकट हो जाए, या

(ख) यदि वह ऐसे स्थान और देश की उत्पत्ति होनी तात्पर्यित है जिसकी उत्पत्ति वह वास्तव में नहीं है; या

(ग) यदि उसे ऐसे नाम से जो किसी अन्य औषधि का है विक्रय किया जाता है या विक्रय के लिए प्रस्थापित अथवा अभिदर्शित किया जाता है; या

(घ) यदि वह इस प्रकार रंजित, विलेपित, चूर्णकृत या पालिश की हुई है कि नुकसान छिप जाता है, या यदि वह उससे बेहतर या अधिक चिकित्सीय

1. यथोक्त की धारा 12 द्वारा उप धारा (1) के स्थान पर (27-7-1964 से) प्रतिस्थापित।

2. 1955 के अधिनियम सं० 11 की धारा 8 द्वारा “राज्य सरकार” के स्थान पर प्रतिस्थापित।

3. 1964 के अधिनियम सं० 13 की धारा 11 द्वारा अनुसूची के स्थान पर (15-9-1964 से प्रतिस्थापित)।

सम्भव हो होनी अभिव्यक्त की जाती है जितना कि वह वास्तव में है ;
या

- (ङ) यदि उस पर लेबल विहित रीति से नहीं लगाया जाता है ; या
- (च) यदि उसके लेबल या पात्र अथवा उसके साथ की किसी चीज पर कोई ऐसा कथन, डिजाइन या आकृति है जो उस औषधि के लिए कोई मिथ्या दावा करती है अथवा जो किसी विशिष्ट में मिथ्या या भुलावा देने वाली है ;
या
- (छ) यदि उसके लेबल या पात्र में उस औषधि का विनिर्माता या उत्पादक होना तात्पर्यित किसी ऐसे व्यष्टि या कम्पनी का नाम है जो व्यष्टि या कम्पनी काल्पनिक है या अस्तित्व में नहीं है ।

¹[17क. मिथ्या छाप वाली प्रसाधन सामग्री—इस धारा के प्रयोजनों के लिए किसी प्रसाधन सामग्री को मिथ्या छाप वाली समझा जाएगा :—

- (क) यदि वह किसी अन्य प्रसाधन सामग्री की नकल है, उसके बदले में है या उससे इस प्रकार मिलती जुलती है कि धोखा हो जाए ; या
- (ख) यदि वह ऐसे स्थान या देश की उत्पत्ति होनी तात्पर्यित है जिसकी उत्पत्ति वह वास्तव में नहीं है ; या
- (ग) यदि उसमें ऐसा रंग है जो विहित नहीं है ; या
- (घ) यदि उसे ऐसे नाम से जो किसी अन्य प्रसाधन सामग्री का है विक्रय किया जाता है या विक्रय के लिए प्रस्थापित अथवा अभिदर्शित किया जाता है ;
या
- (ङ) यदि उस पर लेबल विहित रीति से नहीं लगाया जाता है ; या
- (च) यदि उसके लेबल या पात्र में उस प्रसाधन सामग्री का विनिर्माता या उत्पादक होना तात्पर्यित किसी ऐसे व्यष्टि या कम्पनी का नाम है जो व्यष्टि या कम्पनी काल्पनिक है या अस्तित्व में नहीं है ; या
- (छ) यदि उसके लेबल या पात्र में कोई ऐसा कथन है जो मिथ्या है या किसी विशिष्ट में भुलावा देने वाला है ।]

²[17ख. अपमिश्रित औषधियाँ—इस अध्याय के प्रयोजनों के लिए, किसी औषधि को अपमिश्रित समझा जाएगा :—

- (क) यदि वह पूर्णतः या भागतः किसी गन्दे, गलित या विघटित पदार्थ से बनी है ; या
- (ख) यदि वह अस्वच्छ परिस्थितियों में तैयार की गई, पैक की गई या भंडार में रखी गई है जिससे वह गंदगी से संदूषित हो गई हो या जिससे वह स्वास्थ्य के लिए क्षतिकर हो गई हो ; या

1. 1962 के अधिनियम सं० 21 की धारा 13 द्वारा (27-7-1964 से (अन्तः-स्थापित ।

2. 1964 के अधिनियम सं० 13 की धारा 12 द्वारा (15-5-1964 से) अन्तःस्थापित ।

- (ग) यदि उसका पात्र पूर्णतः या भागतः किसी विषैले या हानिकारक पदार्थ से बना हो जो उसकी अन्तर्वस्तुओं को स्वास्थ्य के लिए क्षतिकर बना दे ; या
- (घ) यदि केवल रंजन के प्रयोजनों के लिए उसमें ऐसा रंग है या अन्तर्विष्ट है जो विहित रंग से भिन्न है ; या
- (ङ) यदि किसी पदार्थ को :—
- (1) उसके साथ मिलाया या पैक किया गया हो जिसमें उसकी क्वालिटी या सामर्थ्य घट जाए ; या
 - (2) पूर्णतः या भागतः उसके बदले में रख दिया गया हो ।

स्पष्टीकरण—खण्ड (क) के प्रयोजनों के लिए किसी औषधि को पूर्णतः या भागतः किसी विघटित पदार्थ से बना केवल इस बात के कारण नहीं समझा जाएगा कि ऐसा विघटित पदार्थ, उस औषधि के लेबल पर विनिर्दिष्ट उस कालावधि के अन्दर, यदि कोई हो, जिसके दौरान उस औषधि का उपयोग किया जाना है उस औषधि के किसी प्राकृतिक विघटन का परिणाम है :

परन्तु तब जब कि ऐसा विघटन उस औषधि के विनिर्माता या उसके ब्योहारी की किसी उपेक्षा के कारण नहीं हुआ है और वह उस औषधि को स्वास्थ्य के लिए क्षतिकर नहीं बनाता है ।]

18. कतिपय औषधियों या प्रसाधन सामग्रियों के विनिर्माण और विक्रय का प्रतिषेध—

उस ¹[तारीख] से जो राज्य सरकार द्वारा शासकीय राजपत्र में अधिसूचना द्वारा इस निमित्त नियत की जाए, कोई व्यक्ति स्वयम् या अपनी ओर से किसी अन्य व्यक्ति द्वारा :—

- (क) निम्नलिखित को विक्रयार्थ विनिर्मित नहीं करेगा या विक्रय नहीं करेगा या स्टोक में नहीं रखेगा या विक्रय के लिए अङ्कित नहीं करेगा या वितरित नहीं करेगा :—

- (i) कोई ऐसी औषधि ²[या प्रसाधन सामग्री] जो मानक क्वालिटी की नहीं है ;

1. (क), (ख), और (ग) खंडों के उपखंडों (i), (ii), (iv) और (v) के लिए 1 अप्रैल, 1947; खण्ड (क) के उपखण्ड (iii) के लिए 1 अप्रैल, 1949 जहां यह दिल्ली अजमेर और कुर्ग में प्रभावी होते हैं देखिए अधिसूचना सं० 18-12-46-डी०-II दिनांक 11-2-1947, 1947 के भारत के राजपत्र भाग 1 पृष्ठ 189 जो अधिसूचना सं० एफ० -I-2148-डी० (ii) दिनांक 29-2-1948 द्वारा यथासंशोधित हुआ । कानूनी नियम आदेश अधिसूचना सं० 664 दिनांक 30-3-1953, 1953 के भारत के राजपत्र के भाग 2 खण्ड 3 पृष्ठ 451 से हिमाचल प्रदेश, बिलासपुर, कच्छ, भोपाल, त्रिपुरा, विन्ध्य प्रदेश और मणिपुर राज्यों के लिए 1 अप्रैल, 1953 ।

2. 1962 के अधिनियम सं० 21 की धारा 14 द्वारा (27-7-1954 से) अन्तः स्थापित ।

- ¹[(ii) कोई मिथ्या छाप वाली औषधि या मिथ्या छाप वाली प्रसाधन सामग्री ;]
- ²[(iik) कोई अपमिश्रित औषधि ;]
- ³[(iii) कोई पेटेन्ट साम्पत्तिक औषधि, जब तक कि उसके लेबल या आधान पर विहित रीति से, उसमें अन्तर्विष्ट संघटकों का सही फारमूला या सूची चिकित्सा वृत्ति के सदस्यों को आसानी से समझ में आ जाने वाली रीति से संप्रदर्शित न हों ;
- (iv) कोई औषधि जो उसके साथ के किसी कथन, डिजाईन या आकृति से या किसी अन्य साधन से, किसी ऐसे रोग या व्याधि का ⁴[निवारण करना, ठीक करना या उसका शमन करना] अथवा कोई ऐसा अन्य प्रभाव जैसा विहित किया जाए रखना तात्पर्यपित करती है या उसका दावा करती है ;
- ⁵(5) कोई प्रसाधन सामग्री जिसमें कोई ऐसा संघटक अन्तर्विष्ट हो जो उसे ऐसे निदेशों के अधीन, जो उपदर्शित किए गए हों या जिनकी सिफारिश की गई हो, प्रयोग के लिए असुरक्षित या अपहानि कर बनाए ;
- (vi) इस अध्याय या तदधीन बनाए गए किसी नियम के उपबन्धों में से किसी के उल्लंघन में कोई औषधि या प्रसाधन सामग्री ;]
- (ख) किसी ऐसी औषधि ⁶[या प्रसाधन सामग्री] का जो इस अधिनियम में या तदधीन बनाए गए किसी नियम के उपबन्धों में से किसी के उल्लंघन में आयात या विनिर्मित की गई है, विक्रय नहीं करेगा या स्टॉक में नहीं रखेगा या विक्रय के लिए अभिदर्शित नहीं करेगा या वितरित नहीं करेगा ;

1. यथोक्त की धारा 14 द्वारा उपखण्ड (ii) के स्थान पर (27-7-1964 से) प्रतिस्थापित ।
2. 1964 के अधिनियम सं० 13 की धारा 13 द्वारा (15-9-1964 से) अन्तःस्थापित ।
3. 1955 के अधिनियम सं० 11 की धारा 9 द्वारा उप-खण्ड (iii) के स्थान पर प्रतिस्थापित ।
4. यथोक्त की धारा 9 द्वारा "निरोग या शमन करने" शब्दों के स्थान पर प्रतिस्थापित ।
5. 1962 के अधिनियम सं० 21 की धारा 14 द्वारा (27-7-64 से) प्रतिस्थापित ।
6. 1962 के अधिनियम सं० 21 की धारा 14 द्वारा (27-7-1964 से) अन्तःस्थापित ।

(ग) किसी औषधि ¹[या प्रसाधन सामग्री] को विक्रयार्थ विनिर्मित या विक्रय या स्टॉक या विक्रयार्थ अभिर्दशित अथवा वितरित इस अध्याय के अधीन ऐसे प्रयोजन के लिए दी गई अनुज्ञप्ति के अधीन और उसकी शर्तों के अनुसार करने के सिवाय नहीं करेगा ;

परन्तु इस धारा की कोई बात परीक्षा, परख या विश्लेषण के प्रयोजन के लिए किसी औषधि के विहित शर्तों के अधीन थोड़े परिमाण में विनिर्माण को लागू नहीं होगी :

परन्तु यह और कि ²[केन्द्रीय सरकार] बोर्ड के साथ परामर्श करने के पश्चात् शासकीय राजपत्र में अधिसूचना द्वारा, उस अधिसूचना में विनिर्दिष्ट किन्हीं शर्तों के अधीन, मानक क्वालिटी की न होने वाली किसी औषधि या औषधियों के वर्ग के विक्रयार्थ विनिर्माण, विक्रय या वितरण की अनुज्ञा दे सकेगी ।

स्पष्टीकरण—खण्ड (क) के उपखण्ड (iii) में वर्णित संघटकों के फारमूला या सूची को उस उपखण्ड का ठीक और पर्याप्त अनुपालन समझा जाएगा यदि संघटकों का पूर्ण और ब्यौरेवार नुस्खा प्रकट किए बिना वह सही तौर से उन सब शक्त या विपैले पदार्थों को जो उसमें अन्तर्विष्ट हों, औषधि की रचना के ठीक-ठीक विवरण सहित, उपदर्शित करती है ।

³[18क. विनिर्माता के नाम आदि का प्रकटन : प्रत्येक व्यक्ति जो किसी औषधि या प्रसाधन सामग्री का विनिर्माता या उसके वितरण के लिए उसका अभिकर्ता नहीं है, अपेक्षा किए जाने पर निरीक्षक को उस व्यक्ति का नाम, पता और अन्य विशिष्टियां प्रकट करेगा जिससे उसने वह औषधि या प्रसाधन सामग्री अर्जित की ।]

19. अभिवाक् (1) इस धारा में इसके पश्चात् यथाउपबंधित के सिवाय, इस अध्याय के अधीन किसी अभियोजन में केवल यह सिद्ध करना कोई प्रतिरक्षा नहीं होगी कि जिस औषधि ⁴[या प्रसाधन सामग्री] के बारे में अपराध किया गया है उस औषधि के प्रकार, पदार्थ या क्वालिटी से या उसके विनिर्माण या आयात की परिस्थितियों से अभियुक्त अनभिज्ञ था, कि क्रेता पर उस विक्रय द्वारा इसलिए कोई प्रतिकूल प्रभाव नहीं पड़ा है क्योंकि उसने उसे केवल परख या विश्लेषण के लिए खरीदा था ।

(2) ⁵[धारा 18 के प्रयोजनों के लिए किसी औषधि का मिथ्या छाप वाली या अपमिश्रित या मानक क्वालिटी से निम्न होना अथवा किसी प्रसाधन सामग्री का मिथ्या

1. 1962 के अधिनियम सं० 21 की धारा 14 द्वारा (27-7-64 से) अन्तः-स्थापित ।
2. 1953 के अधिनियम सं० 11 की धारा 9 द्वारा "राज्य सरकार" के स्थान पर प्रतिस्थापित ।
3. 1964 के अधिनियम सं० 13 की धारा 14 द्वारा (15-4-1964 से) अन्तः-स्थापित ।
4. 1962 के अधिनियम सं० 21 की धारा 15 द्वारा (27-7-1954 से) अन्तःस्थापित ।
5. 1964 के अधिनियम सं० 13 की धारा 15 द्वारा (15-9-1964 से) कुछ शब्दों के स्थान पर प्रतिस्थापित ।

छाप वाली या मानक क्वालिटी से निम्न होना] केवल इस बात के कारण न समझा जाएगा कि—

(क) उसमें कोई अनपकारी पदार्थ या संघटक इस कारण मिलाया गया है कि वह उस औषधि ¹[या प्रसाधन सामग्री] को ऐसी वाणिज्य वस्तु के रूप में, जो वहन या उपभोग के लिए उपयुक्त दशा में हो, विनिर्मित या तैयार करने के लिए अपेक्षित है किन्तु जो उस औषधि ¹[या प्रसाधन सामग्री] के प्रपुंज वजन या मात्रा को बढ़ाने के लिए अथवा उसकी घटिया क्वालिटी या अन्य त्रुटियों को छिपाने के लिए नहीं है; या

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(ख) विनिर्माण, तैयारी या प्रवहण की प्रक्रिया में कोई बाह्य पदार्थ उसके साथ अपरिहार्य रूप में अन्तर्मिश्रित हो चुका है ; परन्तु यह खंड औषधि या प्रसाधन सामग्री के किसी ऐसे विक्रय या वितरण के बारे में लागू नहीं होगा, जो ऐसे अन्तःमिश्रण से विक्रेता या वितरणकर्ता के अवगत हो जाने के पश्चात् होता है ।

³[(3) कोई व्यक्ति जो किसी औषधि या प्रसाधन सामग्री का विनिर्माता अथवा उसके वितरण के लिए उसका अभिकर्ता नहीं है धारा 18 के उल्लंघन के लिए जिम्मेदार उस दशा में नहीं होगा जिसमें वह साबित कर देता है :—

(क) कि उसने उस औषधि या प्रसाधन सामग्री का अर्जन उसके सम्यक् रूप से अनुज्ञप्त विनिर्माता, वितरक या व्यवहारी से किया ;

(ख) कि वह यह नहीं जानता था और युक्तियुक्त तत्परता से अभिनिश्चित नहीं कर सकता था कि वह औषधि या प्रसाधन सामग्री किसी प्रकार उस धारा के उपबन्धों का उल्लंघन करती है ; और

(ग) कि वह औषधि या प्रसाधन सामग्री जब उसके कब्जे में थी तब उचित रूप से भंडारकृत थी और उसी दशा में रही जिसमें वह तब थी जब उसने उसका अर्जन किया था ।]

⁴[20. सरकारी विश्लेषक : (1) राज्य सरकार, शासकीय राजपत्र में अधिसूचना द्वारा विहित अर्हताओं वाले ऐसे व्यक्तियों को, जिन्हें वह ठीक समझती हैं, राज्य में ऐसे क्षेत्रों के लिए

1. 1962 के अधिनियम सं० 21 की धारा 14 द्वारा (27-7-1964 से) अन्तःस्थापित ।

2. 1955 के अधिनियम सं० 11 की धारा 10 द्वारा अन्तः स्थापित खण्ड (कक) का 1964 के अधिनियम सं० 13 की धारा 15 द्वारा (15-9-1964 से) लोप ।

3. 1964 के अधिनियम सं० 13 की धारा 15 द्वारा (15-9-1964 से) प्रतिस्थापित ।

4. 1960 के अधिनियम सं० 35 की धारा 4 द्वारा 20 और 21 मूल उपधारा के स्थान पर (16-3-1961 से) प्रतिस्थापित ।

तथा ऐसी औषधियों या ¹[औषधियों के वर्गों अथवा ऐसी प्रसाधन सामग्रियों या प्रसाधन सामग्रियों के वर्गों] की बाबत जो अधिसूचना में विनिर्दिष्ट हों सरकारी विश्लेषक नियुक्त कर सकेगी।

(2) केन्द्रीय सरकार भी, शासकीय राजपत्र में अधिसूचना द्वारा विहित अर्हताओं वाले ऐसे व्यक्तियों को जिन्हें वह ठीक समझती है ऐसी औषधियों या ¹[औषधियों के वर्गों अथवा ऐसी प्रसाधन सामग्रियों या प्रसाधन सामग्रियों के वर्गों] की बाबत, जो अधिसूचना में विनिर्दिष्ट हों, सरकारी विश्लेषक नियुक्त कर सकेगी।

(3) उपधारा (1) या उपधारा (2) में किसी बात के होते हुए भी न तो केन्द्रीय सरकार और न राज्य सरकार ही किसी ऐसे अधिकारी को जो उसके अधीन सेवा न कर रहा हो उस सरकार की, जिसके अधीन वह सेवा कर रहा हो, पूर्व सम्मति के बिना सरकारी विश्लेषक के रूप में नियुक्त करेगी।

21. निरीक्षक : (1) केन्द्रीय सरकार या राज्य सरकार, शासकीय राजपत्र में अधिसूचना द्वारा, विहित अर्हताओं वाले ऐसे व्यक्तियों को जिन्हें वह ठीक समझती है ऐसे क्षेत्रों के लिए जो उन्हें, यथास्थिति, केन्द्रीय सरकार या राज्य सरकार द्वारा सौंपे जाएं, निरीक्षक नियुक्त कर सकेगी।

(2) शक्तियां जो निरीक्षक द्वारा प्रयुक्त की जा सकेंगी और कर्तव्य जिनका उस द्वारा पालन किया जा सकेगा, औषधि या ²[औषधियों के वर्ग अथवा प्रसाधन सामग्रियों या प्रसाधन सामग्रियों के वर्ग] जिनके संबंध में तथा शर्तें, परिसीमाएं या निबंधन जिनके अध्याधीन ऐसी शक्तियों और कर्तव्यों का प्रयोग या पालन किया जा सकेगा ऐसे होंगे जैसे विहित किए जाएं।

(3) इस धारा के अधीन किसी भी ऐसे व्यक्ति को निरीक्षक नियुक्त नहीं किया जाएगा जिसका ³[औषधियों या प्रसाधन सामग्रियों के आयात, विनिर्माण या विक्रय] में कोई वित्तीय हित हो।

(4) प्रत्येक निरीक्षक भारतीय दण्ड संहिता की धारा 21 (1860 का 45) के अर्थ में लोक सेवक समझा जाएगा और ऐसे प्राधिकारी का शासकीय रूप से अधीनस्थ होगा जिसे उसे नियुक्त करने वाली सरकार इस निमित्त विनिर्दिष्ट करे।]

⁴[22. **निरीक्षकों की शक्तियां :** (1) धारा 23 के, और इस निमित्त केन्द्रीय सरकार द्वारा बनाए गए किन्हीं नियमों के, उपबंधों के अध्याधीन कोई निरीक्षक उस क्षेत्र की उन

1. 1962 के अधिनियम सं० 21 की धारा 16 द्वारा "औषधियों के वर्ग" के स्थान पर (27-9-1964 से) प्रतिस्थापित।

2. यथोक्त की धारा 17 द्वारा "औषधियों के वर्ग" शब्दों के स्थान पर (27-7-1964 से) प्रतिस्थापित।

3. 1962 के अधिनियम सं० 21 की धारा 17 द्वारा "औषधियों के विनिर्माण आयात या विक्रय में" के स्थान पर (27-7-1964 से) प्रतिस्थापित।

4. 1955 की अधिनियम सं० 11 की धारा 11 द्वारा 22 के स्थान पर प्रतिस्थापित।

स्थानीय सीमाओं के अन्दर, जिसके लिए वह नियुक्त किया गया है :—

- (क) ऐसे किसी परिसर का निरीक्षण कर सकेगा जिसमें कोई औषधि ¹[या प्रसाधन सामग्री] विनिर्मित की जा रही है और सीरम, वैक्सीन और इस निमित्त विहित किसी अन्य औषधि की अवस्था में उसके विनिर्माण के संयंत्र और विनिर्माण की प्रक्रिया और औषधि के मानकीकरण और परख के लिए काम में लाए जाने वाले साधनों का निरीक्षण कर सकेगा ;
- (ख) ऐसी किसी औषधि ¹[या प्रसाधन सामग्री] के नमूने ले सकेगा जो विनिर्मित की जा रही है, या विक्रय की जा रही है, या विक्रयार्थ भण्डारकृत की जा रही है या प्रदर्शित की जा रही या वितरित की जा रही है ;
- (ग) किसी ऐसे स्थान में, जिसकी बाबत उसके पास यह विश्वास करने का कारण है कि इस अध्याय के अधीन अपराध किया जा चुका है या किया जा रहा है सब युक्तियुक्त समयों पर ऐसे सहायकों के साथ, यदि कोई हों, जिन्हें वह आवश्यक समझता है, प्रवेश कर सकेगा, और तलाशी ले सकेगा और उस व्यक्ति को, जिसके कब्जे में वह औषधि ¹[या प्रसाधन सामग्री] है, जिसके बारे में अपराध किया जा चुका है या किया जा रहा है, बीस दिनों से अधिक की विनिर्दिष्ट कालावधि तक ऐसी औषधि ¹[या प्रसाधन सामग्री] के किसी स्टॉक का व्ययन न करने का लिखित आदेश दे सकेगा या जब तक अधिकृत अपराध ऐसा न हो कि वह त्रुटि औषधि ¹[या प्रसाधन सामग्री] के कब्जाधारी द्वारा दूर की जा सकती है, ऐसी औषधि ¹[या प्रसाधन सामग्री] के स्टॉक को अभिगृहीत कर सकेगा ;
- ²[(गग) खण्ड (ग) में वर्णित किसी स्थान में पाए गए किसी अभिलेख, रजिस्टर दस्तावेज या किसी अन्य भौतिक पदार्थ की परीक्षा कर सकेगा और यदि उसके पास यह विश्वास करने का कारण है कि वह इस अधिनियम या तदधीन बनाए गए नियमों के अधीन दण्डनीय किसी अपराध के किए जाने का साक्ष्य हो सकता है तो उसे अभिगृहीत कर सकेगा ;]
- (घ) ऐसी अन्य शक्तियों का प्रयोग कर सकेगा, जो इस अध्याय या तदधीन बनाए गए किन्हीं नियमों के प्रयोजनों को कार्यान्वित करने के लिए आवश्यक हों ।

(2) दंड प्रक्रिया संहिता, 1898 (1898 का 5) के उपबन्ध इस अध्याय के अधीन तलाशी या अभिग्रहण को यथाशक्य वैसे ही लागू होंगे जैसे वे उक्त संहिता की धारा 98 के अधीन निकाले गए वारंट के प्राधिकार के अधीन की गई किसी तलाशी या अभिग्रहण को लागू होते हैं ।

1. 1962 के अधिनियम सं० 21 की धारा 18 द्वारा (27-7-1964 से) अन्तःस्थापित ।

2. 1960 के अधिनियम सं० 35 की धारा 5 द्वारा (16-3-1961 से) अन्तःस्थापित ।

(3) यदि कोई व्यक्ति इस अध्याय के द्वारा या अधीन किसी निरीक्षक को प्रदत्त शक्तियों के प्रयोग में, उसको जानबूझकर बाधित करेगा तो वह कारावास से, जो तीन वर्ष तक का हो सकेगा, या जुर्माने से अथवा दोनों से दंडनीय होगा।

23. निरीक्षकों की प्रक्रिया : (1) जहां कोई निरीक्षक इस अध्याय के अधीन किसी औषधि ¹[या प्रसाधन सामग्री] का नमूना लेता है वहां वह उसकी उचित कीमत निविदत्त करेगा, और उसके लिए लिखित अभिस्वीकृति अपेक्षित कर सकेगा।

(2) जहां उपधारा (1) के अधीन निविदत्त कीमत लेने से इन्कार किया जाता है, या जहां कोई निरीक्षक धारा 22 के खंड (ग) के अधीन किसी औषधि ¹[या प्रसाधन सामग्री] के स्टॉक को अभिग्रहीत करता है वहां वह उसके लिए विहित प्ररूप में पावती का निविदान करेगा।

(3) जहां कोई निरीक्षक किसी औषधि ¹[या प्रसाधन सामग्री] का नमूना, परख या विश्लेषण के लिए लेता है वहां वह ऐसे प्रयोजन की विहित प्ररूप में लिखकर उस व्यक्ति को प्रज्ञापना देगा, जिससे उसको लेता है, और ऐसे व्यक्ति की उपस्थिति में, जब तक कि वह जानबूझकर स्वयं अनुपस्थित नहीं हो जाता, उस नमूने को चार प्रभागों में विभक्त करेगा और उन्हें प्रभावी रूप से मुहरबन्द और उपयुक्त रूप से चिह्नित करेगा और ऐसे मुहरबन्द और चिह्नित सब या किन्हीं प्रभागों पर ऐसे व्यक्ति को अपनी मुहर और चिह्न लगाने देगा :

परन्तु जहां नमूना उस परिसर से लिया जाता है, जहां औषधि ¹[या प्रसाधन सामग्री] विनिर्मित की जा रही है, वहां नमूने को केवल तीन प्रभागों में विभक्त करना आवश्यक होगा :

परन्तु यह और कि जहां औषधि ¹[या प्रसाधन सामग्री] छोटे आकार के पात्रों में बनाई गई हैं, वहां पूर्वोक्त रूप में नमूने को विभक्त करने की बजाय निरीक्षक उक्त पात्रों में से, यथास्थिति, तीन या चार को समुचित रूपेण चिह्नित करके और जहां आवश्यक हो वहां मुहरबन्द करके ले सकेगा और यदि वह औषधि ¹[या प्रसाधन सामग्री] ऐसी है कि उच्छन्न रहने से उसके क्षय होने या अन्यथा खराब हो जाने की सम्भाव्यता है, तो लेगा।

(4) निरीक्षक ऐसे विभक्त किए गए नमूने का, यथास्थिति, एक प्रभाग या एक पात्र उस व्यक्ति को लौटाएगा जिससे वह उसको लेता है, और अवशेष को प्रतिधृत रखेगा, और उसका व्ययन निम्नलिखित रूप में करेगा, अर्थात् :—

- (i) एक प्रभाग या पात्र को तुरन्त सरकारी विश्लेषक को परख या विश्लेषण के लिए भेजेगा ;
- (ii) दूसरे को वह उस न्यायालय में पेश करेगा, जिसके समक्ष उस औषधि ¹[या प्रसाधन सामग्री] के बारे में कार्यवाहियां, यदि कोई हों, संस्थित की गई हैं, और

²(iii) तीसरे को, जहां कि वह लिया गया हो, उस व्यक्ति को, यदि कोई हो, भेजेगा जिसका नाम, पता और अन्य विशिष्टियां धारा 18 क के अधीन प्रकट की गई हैं]

(5) जहां कोई निरीक्षक धारा 22 के खण्ड (ग) के अधीन कोई कार्रवाई करता है, वहां :—

(क) वह यह अभिनिश्चित करने के लिए पूरी शीघ्रता से कार्रवाई करेगा कि वह औषधि ¹[या प्रसाधन सामग्री] धारा 18 के उपबंधों में से किसी का उल्लंघन करती है या नहीं और यदि वह अभिनिश्चित हो गया है कि वह औषधि ¹[या प्रसाधन सामग्री] ऐसा उल्लंघन नहीं करती है तो उक्त खंड के अधीन पारित आदेश को तुरन्त प्रतिसंहृत करेगा, या, यथास्थिति, ऐसे अभिग्रहीत स्टॉक की वापसी के लिए ऐसी कार्रवाई करेगा जैसी आवश्यक हो ;

(ख) यदि वह औषधि ¹[या प्रसाधन सामग्री] के स्टॉक का अभिग्रहण करता है तो वह यथाशक्य शीघ्रता से मजिस्ट्रेट को उसकी इत्तिला देगा और उसकी अभिरक्षा के सम्बन्ध में उसके आदेश लेगा ;

(ग) किसी अभियोजन के संस्थित किए जाने पर प्रतिकूल प्रभाव डाले बिना यह है कि यदि अभिकथित उल्लंघन ऐसा है कि त्रुटि का उपचार औषधि ¹[या प्रसाधन सामग्री] के कब्जाधारी द्वारा किया जा सकता है तो वह अपना यह समाधान हो जाने पर कि त्रुटि का वैसा उपचार किया जा चुका है, उक्त खंड के अधीन अपने आदेश का तुरन्त प्रतिसंहरण करेगा ।

²[(6) जहां कोई निरीक्षक धारा 22 की उपधारा (1) के खण्ड (गग) के अधीन किसी अभिलेख, रजिस्टर, दस्तावेज या किसी अन्य भौतिकी पदार्थ का अभिग्रहण करता है वहां वह यथाशक्य शीघ्रता से मजिस्ट्रेट को उसकी इत्तिला देगा और उसकी अभिरक्षा के सम्बन्ध में उसके आदेश लेगा ।

24. व्यक्तियों का उस स्थान को प्रकट करने के लिए आबद्ध होना जहां औषधि या प्रसाधन सामग्रियां विनिर्मित की जाती या रखी जाती हैं : प्रत्येक ऐसा व्यक्ति, जो किन्हीं ऐसे परिसरों का, जिनमें कोई औषधि ¹[या प्रसाधन सामग्री] विनिर्मित की जा रही है या विक्रय अथवा वितरण के लिए रखी जाती है, तत्समय के लिए भारसाधक है, निरीक्षक को वह स्थान

1. 1962 के अधिनियम सं० 21 की धारा 15 द्वारा (27-7-1964) से अन्तःस्थापित ।

2. 1964 के अधिनियम सं० 13 की धारा 16 द्वारा खंड (iii) के स्थान पर (15-9-1964 से) प्रतिस्थापित ।

3. 1960 के अधिनियम सं० 35 की धारा 6 द्वारा (16-3-1961 से) अन्तःस्थापित ।

जहाँ वह औषधि ¹[या प्रसाधन सामग्री], यथास्थिति, विनिर्मित की जा रही है या विक्रय अथवा वितरण के लिए रखी है, प्रकट करने के लिए, उस दशा में वैध रूप से आवद्ध होगा जिसमें वह वैसा करने के लिए निरीक्षक द्वारा अपेक्षित किया जाए।

25. सरकारी विश्लेषकों की रिपोर्टें : (1) सरकारी विश्लेषक, जिसे परख या विश्लेषण के लिए किसी औषधि ¹[या प्रसाधन सामग्री] का नमूना धारा 23 की उपधारा (4) के अधीन भेजा गया है, विहित प्ररूप में तीन प्रतियों में एक हस्ताक्षरित रिपोर्ट उस नमूने को भेजने वाले निरीक्षक को परिदत्त करेगा।

(2) उसकी प्राप्ति पर निरीक्षक उस रिपोर्ट की एक प्रति उस व्यक्ति को, जिससे नमूना लिया गया था, ²[और दूसरी प्रति ऐसे व्यक्ति को, यदि कोई हो, जिसका नाम, पता और अन्य विशिष्टियाँ धारा 18क के अधीन प्रकट की गई हैं,] परिदत्त करेगा, और तीसरी प्रति को नमूने के बारे में किसी अभियोजन में उपयोग किए जाने के लिए प्रतिधृत रखेगा।

(3) कोई दस्तावेज, जो इस अध्याय के अधीन सरकारी विश्लेषक द्वारा हस्ताक्षरित रिपोर्ट होनी तात्पर्यित है उसमें कथित तथ्यों का साक्ष्य होगी, और ऐसा साक्ष्य निश्चायक होगा जब तक कि उस व्यक्ति ने, जिससे नमूना लिया गया था, ³[या उस व्यक्ति ने जिसका नाम, पता और अन्य विशिष्टियाँ धारा 18क के अधीन प्रकट की गई हैं,] रिपोर्ट की एक प्रति की प्राप्ति के अट्ठाइस दिन के अन्दर निरीक्षक या न्यायालय को जिसके समक्ष नमूने के बारे में कोई कार्यवाहियाँ लम्बित हैं लिखकर अधिसूचित न कर दिया हो कि वह रिपोर्ट के प्रतिवाद में साक्ष्य पेश करने का आशय रखता है।

(4) उस दशा के सिवाय जिसमें नमूने की परख या उसका विश्लेषण केन्द्रीय औषधि प्रयोगशाला में पहले ही हो गया हो, जहाँ किसी व्यक्ति ने सरकारी विश्लेषक की रिपोर्ट के प्रतिवाद में साक्ष्य पेश करने का अपना आशय उपधारा (3) के अधीन अधिसूचित कर दिया है वहाँ न्यायालय स्वप्रेरणा से या परिवादी अथवा अभियुक्त में से किसी की प्रार्थना पर स्वविवेकानुसार उस औषधि ¹[या प्रसाधन सामग्री] के नमूने को जो धारा 23 की उपधारा (4) के अधीन मजिस्ट्रेट के समक्ष पेश किया गया है उक्त प्रयोगशाला को परख या विश्लेषण के लिए भिजवा सकेगा जो परख या विश्लेषण करेगी और उसके परिणाम की केन्द्रीय औषधि प्रयोगशाला निदेशक द्वारा हस्ताक्षरित या उसके प्राधिकाराधीन लिखित रिपोर्ट देगी और ऐसी रिपोर्ट उसमें कथित तथ्यों का निश्चायक साक्ष्य होगी।

(5) केन्द्रीय औषधि प्रयोगशाला द्वारा उपधारा (4) के अधीन की गई परख या विश्लेषण का खर्चा परिवादी अथवा अभियुक्त द्वारा संदत्त किया जाएगा जैसा भी न्यायालय निदिष्ट करे।

¹ 1962 के अधिनियम सं० 21 की धारा 15 द्वारा (27-7-1964 से) अन्तः स्थापित।

² 1964 के अधिनियम सं० 13 की धारा 17 द्वारा शब्दों के स्थान पर (15-9-1964) प्रतिस्थापित।

³ अथोक्त की धारा 17 द्वारा "या उक्त वारन्टर" शब्दों के स्थान पर (15-9-1964 से) प्रतिस्थापित।

26. औषधि या प्रसाधन सामग्री के क्रेता का परख या विश्लेषण कराने के लिए समर्थ होना : कोई भी व्यक्ति अपने द्वारा क्रीत किसी औषधि ¹[या प्रसाधन सामग्री] को विहित रीति में आवेदन करके और विहित फीस देकर परख या विश्लेषण के लिए सरकारी विश्लेषक को भेजने का और ऐसी परख या विश्लेषण की सरकारी विश्लेषक द्वारा हस्ताक्षरित रिपोर्ट प्राप्त करने का हकदार होगा।

²[27. इस अध्याय के उल्लंघन में औषधियों के विनिर्माण, विक्रय आदि के लिए शास्ति : जो कोई स्वयम् या अपनी ओर से किसी अन्य व्यक्ति द्वारा निम्नलिखित का अर्थात् :—

(क) किसी औषधि का —

(i) जो धारा 17 के खण्ड (क), खण्ड (ख), खण्ड (ग), खण्ड (घ), खण्ड (च) या खण्ड (छ) के अधीन मिथ्या छाप वाली अथवा धारा 17 (ख) के अधीन, अपमिश्रित समझी जाती है ; या

(ii) धारा 18 के खण्ड (ग) के अधीन यथाअपेक्षित विधिमान्य अनुज्ञप्ति के बिना ;

विक्रयार्थ विनिर्माण करेगा, विक्रय करेगा, विक्रयार्थ भंडार में रखेगा या प्रदर्शित करेगा या वितरित करेगा वह कारावास से, जिसकी अवधि एक वर्ष से कम न होगी किन्तु जो दस वर्ष तक की हो सकेगी दण्डनीय होगा और जुर्माने का भी दायी होगा :

परन्तु न्यायालय, लेखबद्ध किए जाने वाले किन्हीं विशेष कारणों के लिए, एक वर्ष से कम के कारावास का दण्ड अधिरोपित कर सकेगा ;

(ख) खण्ड (क) में निर्दिष्ट औषधि से भिन्न किसी औषधि का, इस अध्याय या तदधीन बनाए गए किसी नियम के उपबन्धों में से किसी के उल्लंघन में विक्रयार्थ विनिर्माण करेगा, विक्रय करेगा, विक्रयार्थ भंडार में रखेगा या प्रदर्शित करेगा या वितरित करेगा वह कारावास से, जिसकी अवधि तीन वर्ष तक की हो सकेगी, या जुर्माने से अथवा दोनों से दण्डनीय होगा।]

³[27क. इस अध्याय के उल्लंघन में प्रसाधन सामग्रियों के विनिर्माण, विक्रय आदि के लिए शास्ति : जो कोई स्वयम् या अपनी ओर से किसी अन्य व्यक्ति द्वारा किसी प्रसाधन सामग्री का इस अध्याय या तदधीन बनाए गए किसी नियम के उपबन्धों में से किसी के उल्लंघन में विक्रयार्थ विनिर्माण करेगा, विक्रय करेगा, विक्रयार्थ भंडार में रखेगा या प्रदर्शित करेगा या वितरित करेगा वह कारावास से, जिसकी अवधि एक वर्ष तक की हो सकेगी या जुर्माने से, जो पांच सौ रुपए तक का हो सकेगा, अथवा दोनों से, दण्डनीय होगा।

¹1962 के अधिनियम सं० 21 की धारा 15 द्वारा (27-7-1964 से) अन्तःस्थापित।

²1964 के अधिनियम सं० 18 की धारा 18 द्वारा धारा 27, के स्थान पर (15-9-1964 से) प्रतिस्थापित।

³1962 के अधिनियम सं० 21 की धारा 19 द्वारा (27-7-1964 से) अन्तःस्थापित।

¹[28. विनिर्माता आदि का नाम प्रकट न करने के लिए शास्ति : जो कोई धारा 18 क के उपबन्धों का उल्लंघन करेगा वह कारावास से, जिसकी अवधि एक वर्ष तक की हो सकेगी, या जुर्माने से, जो पांच सौ रुपए तक का हो सकेगा, अथवा दोनों से दण्डनीय होगा ।]

29. सरकारी विश्लेषण की रिपोर्ट का विज्ञापन के लिए उपयोग करने के लिए शास्ति : जो कोई केन्द्रीय औषधि प्रयोगशाला द्वारा या सरकारी विश्लेषक द्वारा की गई परख या विश्लेषण की किसी रिपोर्ट का या ऐसी रिपोर्ट के किसी उद्धरण का उपयोग किसी औषधि ² [या प्रसाधन सामग्री] के विज्ञापन के प्रयोजन के लिए करेगा वह जुर्माने से, जो पांच सौ रुपए तक का हो सकेगा, दण्डनीय होगा ।

³[30. पश्चात्तर्वर्ती अपराधों के लिए शास्ति : ⁴[(1) जो कोई किसी ऐसे अपराध का सिद्धदोष होने पर —

(क) जो धारा 27 के खण्ड (क) के अधीन अपराध है उस खण्ड के अधीन अपराध का पुनः सिद्धदोष होगा वह कारावास से, जिसकी अवधि दो वर्ष से कम न होगी किन्तु जो ⁵[दस वर्ष] तक की हो सकेगी दण्डनीय होगा और जुर्माने का भी दायी होगा :—

परन्तु न्यायालय, लेखबद्ध किए जाने वाले किन्हीं विशेष कारणों के लिए दो वर्ष से कम के कारावास का दण्ड अधिरोपित कर सकेगा ;

(ख) जो धारा 27 के खण्ड (ख) के अधीन अपराध है उस खण्ड के अधीन अपराध का पुनः सिद्धदोष होगा वह कारावास से, जिसकी अवधि ⁵[दस वर्ष] तक की हो सकेगी या जुर्माने से, अथवा दोनों से, दण्डनीय होगा ।]

⁶[(1क) जो कोई धारा 27 क के अधीन किसी अपराध का सिद्धदोष होने पर उस धारा के अधीन पुनः सिद्धदोष होगा वह कारावास से, जिसकी अवधि दो वर्ष तक की हो सकेगी, या जुर्माने से, अथवा दोनों से, दण्डनीय होगा ।]

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1. 1964 के अधिनियम सं० 13 की धारा 19 द्वारा धारा 28 के स्थान पर (15-9-1964) प्रतिस्थापित ।
 2. 1962 के अधिनियम सं० 21 की धारा 15 द्वारा (27-7-1964) से अन्तःस्थापित
 3. 1955 के अधिनियम सं० 11 की धारा 14 द्वारा धारा 30 के स्थान पर प्रतिस्थापित ।
 4. 1960 के अधिनियम सं० 35 की धारा 8 द्वारा उपधारा (झ) के स्थान पर (16-3-1961 से) प्रतिस्थापित ।
 5. 1964 के अधिनियम सं० 13 की धारा 20 द्वारा पांच वर्ष के स्थान पर (15-9-1964 से) प्रतिस्थापित ।
 6. 1962 के अधिनियम सं० 21 की धारा 20 द्वारा (27-7-1964 से) अन्तःस्थापित ।

- (2) जो कोई धारा 29 के अधीन^{1****} अपराध का सिद्धदोष होने पर किसी धारा के अधीन अपराध का पुनः सिद्धदोष होगा वह कारावास से, जो ²[दस वर्ष]⁸ तक का हो सकेगा, या जुर्माने से, अथवा दोनों से दण्डनीय होगा।

31. अधिहरण। ³[(1)] जहां कोई व्यक्ति इस अध्याय या तदधीन बनाए गए किसी नियम के किसी ऐसे उपबन्ध के, जो इस निमित्त बनाए गए नियम द्वारा विनिर्दिष्ट हो, उल्लंघन के लिए इस अध्याय के अधीन सिद्धदोष किया गया है वहां उस औषधि ⁴[या प्रसाधन सामग्री] का स्टॉक ⁵[जिसके सम्बन्ध में उल्लंघन हुआ है अधिहरणीय होगा और यदि ऐसा उल्लंघन—

- (i) किसी ऐसी औषधि के विनिर्माण की बाबत है जो धारा 17 के खण्ड (क), खण्ड (ख), खण्ड (ग), खण्ड (घ), खण्ड (च) या खण्ड (छ) के अधीन मिथ्या छाप वाली अथवा धारा 17 ख के अधीन अपमिश्रित समझी जाती है ; या
- (ii) धारा 18 के खण्ड (ग) के अधीन यथाअपेक्षित विधिमान्य अनुज्ञप्ति के बिना किसी औषधि के विक्रयार्थ विनिर्माण या विक्रय, या विक्रयार्थ भंडार में रखने या प्रदर्शित करने या वितरण की बाबत है ;

तो ऐसे विनिर्माण, विक्रय या वितरण में प्रयुक्त कोई उपकरण या मशीनरी और कोई ऐसे पात्र, पकेज या आवेष्टक जिनमें ऐसी औषधि अन्तर्विष्ट है तथा ऐसी औषधि के प्रवहण में प्रयुक्त पशु, गाड़ियां, यान या अन्य प्रवहण भी अधिहरणीय होंगे।]

⁶(2) उपधारा (1) में अन्तर्विष्ट उपबंधों पर प्रतिकूल प्रभाव डाले बिना यह है कि जहां किसी निरीक्षक के आवेदन पर या अन्यथा तथा ऐसी जांच के पश्चात् जैसी आवश्यक हो न्यायालय का समाधान हो जाता है कि वह औषधि या प्रसाधन सामग्री मानक क्वालिटी की नहीं है अथवा ⁷[मिथ्या छाप वाली या अपमिश्रित औषधि] या मिथ्या छाप वाली

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1. 1964 की अधिनियम सं० 13 की धारा 20 द्वारा धारा 28 “या” शब्दों और अंकों का 15-9-1964 से लोप।
 2. यथोक्त की धारा 20 द्वारा “दो वर्ष” के स्थान पर प्रतिस्थापित।
 3. 1960 के अधिनियम सं० 35 की धारा 9 द्वारा 16-3-1961 से (झ) उपधारा के रूप में पुनर्न्यायिकृत।
 4. 1962 के अधिनियम सं० 21 की धारा 21 द्वारा (27-7-1964 से) अन्तःस्थापित।
 6. 1964 के अधिनियम सं० 13 की धारा 21 द्वारा (15-9-1964 से) जोड़ा।
 6. 1960 के अधिनियम सं० 35 की धारा 9 द्वारा अन्तःस्थापित उपधारा (2) को 1962 के अधिनियम सं० 21 की धारा 21 द्वारा (27-7-1964 से) प्रतिस्थापित।
 7. 1964 के अधिनियम सं० 13 की धारा 21 द्वारा “मिथ्या छापवाली औषधि है” के स्थान पर (15-3-1964 से) प्रतिस्थापित।

प्रसाधन सामग्री है वहां यथास्थिति ऐसी औषधि या ऐसी प्रसाधन सामग्री अधिहरणीय होगी।]

¹[31क. सरकारी विभागों को उपबंधों का लागू होना : धारा 31 में अन्तर्विष्ट उपबंधों के सिवाय इस अध्याय के उपबंध सरकार के किसी विभाग द्वारा औषधियों के विनिर्माण, विक्रय या वितरण के सम्बन्ध में वैसे ही लागू होंगे जैसे वे किसी अन्य व्यक्ति द्वारा औषधियों के विनिर्माण, विक्रय या वितरण के सम्बन्ध में लागू होते हैं।]

32. अपराधों का संज्ञान : (1) इस अध्याय के अधीन कोई अभियोजन निरीक्षक द्वारा संस्थित किए जाने के सिवाय संस्थित नहीं किया जाएगा।

(2) प्रेसिडेंसी मजिस्ट्रेट या प्रथम वर्ग के मजिस्ट्रेट से अवर कोई न्यायालय इस अध्याय के अधीन दण्डनीय अपराध का विचारण नहीं करेगा।

(3) इस अध्याय में अन्तर्विष्ट कोई बात किसी व्यक्ति का किसी ऐसे कार्य या लोप के लिए, जो इस अध्याय के खिलाफ अपराध बनता है, किसी अन्य विधि के अधीन अभियोजन निवारित करने वाली नहीं समझी जाएगी।

²[32क. विनिर्माता आदि को अभियोजित करने की न्यायालय की शक्ति : जहां इस अध्याय के अधीन किसी ऐसे अपराध के जिसका किसी ऐसे व्यक्ति द्वारा किया जाना अभिकथित है जो किसी औषधि या प्रसाधन सामग्री का विनिर्माता, अथवा उसके वितरणार्थ उसका अभिकर्ता नहीं है, विचारण के दौरान किसी समय न्यायालय का अपने समक्ष पेश किए गए साक्ष्य पर यह समाधान हो जाता है कि ऐसा विनिर्माता या अभिकर्ता भी उस अपराध से सम्बद्ध है वहां तब, दण्ड प्रक्रिया संहिता 1898 (1898 का 5) की धारा 351 की उपधारा (1) में अन्तर्विष्ट किसी बात के होते हुए भी, न्यायालय उसके खिलाफ ऐसे कार्यवाही कर सकेगा मानो उसके खिलाफ धारा 32 के अधीन अभियोजन संस्थित किया गया हो।]

33. नियम बनाने की केन्द्रीय सरकार की शक्ति : ³(1) केन्द्रीय सरकार बोर्ड के साथ परामर्श करने के पश्चात् और शासकीय राजपत्र में अधिसूचना द्वारा पूर्व प्रकाशन के पश्चात्, इस अध्याय के उपबंधों को प्रभावी करने के प्रयोजन के लिए नियम बना सकेगी :

परन्तु यदि केन्द्रीय सरकार की यह राय हो कि ऐसी परिस्थितियां पैदा हो गई हैं, जिनसे आवश्यक हो गया है कि बोर्ड के साथ ऐसे परामर्श के बिना नियम बना लिए जाएं तो बोर्ड के साथ परामर्श अभिमोचित किया जा सकेगा, किन्तु ऐसी दशा में नियम बना लेने

¹ 1954 के अधिनियम सं० 13 की धारा 22 द्वारा (15-9-1964 से) अन्तःस्थापित।

² यथोक्त की धारा 29 द्वारा (15-9-1964 से) अन्तःस्थापित।

³ 1955 के अधिनियम सं० 11 की धारा 15 द्वारा उपधारा (अ) प्रतिस्थापित।

के छह मास के अन्दर बोर्ड से परामर्श किया जाएगा और केन्द्रीय सरकार किन्हीं भी ऐसे सुझावों पर, जो बोर्ड उक्त नियमों के संशोधन के सम्बन्ध में दे, विचार करेगी।]

(2) पूर्वगामी शक्ति की व्यापकता पर प्रतिकूल प्रभाव डाले बिना ऐसे नियम —

- (क) औषधियों ¹[या प्रसाधन सामग्रियों] की परख और विश्लेषण के लिए प्रयोगशालाओं की स्थापना के वास्ते उपबन्ध कर सकेंगे ;
- (ख) सरकारी विश्लेषकों की अर्हताएं और कर्तव्य तथा निरीक्षकों की अर्हताएं विहित कर सकेंगे।
- (ग) यह अवधारण करने में की जाने वाली परख या विश्लेषण के ढंग विहित कर सकेंगे कि क्या कोई औषधि ¹[या प्रसाधन सामग्री] मानक क्वालिटी की हैं ;
- (घ) जीवी और अंग-घात्विक सम्मिश्रणों के सम्बन्ध में मानकीकरण की इकाइयां या ढंग विहित कर सकेंगे ;

²[(घघ) धारा 17ख के खण्ड (घ) के अधीन उस रंग या उन रंगों को विहित कर सकेंगे जो रंजन के प्रयोजनों के लिए किसी औषधि में हों या अन्तर्विष्ट हो सकेंगे] ;

(ङ) औषधियों या किसी विनिर्दिष्ट औषधि या औषधियों के वर्ग ³[अथवा प्रसाधन सामग्रियों या किसी विनिर्दिष्ट प्रसाधन सामग्री या प्रसाधन सामग्रियों के वर्ग] के विक्रयार्थ विनिर्माण के लिए, विक्रय के लिए और वितरण के लिए अनुज्ञप्तियों के प्ररूप, ऐसी अनुज्ञप्तियों के लिए आवेदन का प्ररूप वे शर्तें जिनके अधीन ऐसी अनुज्ञप्तियां दी जा सकेंगी उनको देने के लिए सशक्त प्राधिकारी और उनके लिए देय फीसें विहित कर सकेंगे ;

(च) उन रोगों और व्याधियों को जिनका ⁴[निवारण, ठीक या शमन करना] तात्पर्यित या उसका दावा कोई औषधि नहीं करती और ऐसे अन्य प्रभावों को जिनका रखना तात्पर्यित या उसका दावा ऐसी औषधि नहीं करती, विनिर्दिष्ट कर सकेंगे ;

¹ 1962 के अधिनियम सं० 21 की धारा 14 द्वारा (27-7-1964 से) अन्तःस्थापित।

² 1964 के अधिनियम सं० 13 की धारा 24 द्वारा (15-9-1964 से) अन्तःस्थापित।

³ 1962 के अधिनियम सं० 21 की धारा 22 द्वारा (27-7-1964 से) अन्तःस्थापित।

⁴ 1955 के अधिनियम सं० 11 की धारा 15 द्वारा "निरोग और शमन करने" के स्थान पर प्रतिस्थापित।

- (छ) ऐसी शर्तों को विहित कर सकेंगे, जिन्हें अधीन रहते हुए औषधियों की परीक्षा, परख या विश्लेषण के प्रयोजन के लिए थोड़े परिमाण में विनिर्मित किया जा सकेगा ;
- (ज) यह अपेक्षित कर सकेंगे कि किसी विनिर्दिष्ट औषधि या औषधियों के वर्ग के विनिर्माण की तारीख और शक्तता के अवसान की तारीख उनके लेबल या अन्तर्वेष्टक पर स्पष्टतः और सही रूप में कथित की जाए तथा उक्त औषधि या औषधियों के वर्ग का, उसके विनिर्माण की तारीख से एक विनिर्दिष्ट कालावधि के पश्चात् या शक्तता की तारीख के अवसान के पश्चात् विनियम, विक्रयार्थ भंडारकरण या प्रदर्शन अथवा वितरण प्रतिषिद्ध कर सकेंगे ;
- (झ) औषधियों ¹[या प्रसाधन सामग्रियों] को बोतलों, पैकेजों और अन्य आधनों में पैक करने में पालनीय शर्तें विहित कर सकेंगे और ऐसी शर्तों के उल्लंघन में पैक की गई औषधियों या प्रसाधन सामग्रियों का विनियम, विनियमार्थ भंडारकरण या प्रदर्शन अथवा वितरण प्रतिषिद्ध कर सकेंगे ;
- (ञ) पैक की गई औषधियों ¹[या प्रसाधन सामग्रियों] पर लेबल लगाने का तरीका विनियमित कर सकेंगे, और वे बातें विहित कर सकेंगे जो ऐसे लेबलों में हो सकेंगी या नहीं हो सकेंगी ;
- (ट) ऐसे किसी विषैले पदार्थ के अधिकतम अनुपात को विहित कर सकेंगे, जो किसी औषधि में मिलाया जा सकेगा या अन्तर्विष्ट किया जा सकेगा, जिस किसी औषधि का, जिसमें वह अनुपात अधिक हो गया है, विनिर्माण, विक्रय या विक्रयार्थ भंडारकरण या प्रदर्शन अथवा वितरण प्रतिषिद्ध कर सकेंगे और उन पदार्थों को विनिर्दिष्ट कर सकेंगे, जो इस अध्याय और तदधीन बनाए गए नियमों के प्रयोजनार्थ विषैले समझे जाएंगे ;
- (ठ) यह अपेक्षित कर सकेंगे कि किसी विनिर्दिष्ट औषधि का स्वीकृत वैज्ञानिक नाम ऐसी किसी पेटेन्ट या साम्प्रतिक औषधि के लेबल या आवेष्टक पर, जिसमें ऐसी औषधि अन्तर्विष्ट है, विहित रीति में सम्प्रदर्शित किया जाए ;
- ²[* * * * *]
- ³(ड) निरीक्षकों की शक्तियां और कर्तव्य विहित कर सकेंगे और ⁴[वह औषधि या औषधियों के वर्ग अथवा प्रसाधन सामग्रियां या प्रसाधन सामग्रियों के

¹ 1962 के अधिनियम सं० 21 की धारा 14 द्वारा (27-7-1964 से) अन्तःस्थापित ।

² 1954 के अधिनियम सं० 13 की धारा 24 द्वारा (15-9-1964 से) खण्ड (ड) का लोप ।

³ 1960 के अधिनियम सं० 35 की धारा 10 द्वारा (16-3-1961 से) खण्ड (ड) के स्थान पर प्रतिस्थापित ।

⁴ ¹1962 के अधिनियम सं० 21 की धारा 22 द्वारा (27-7-1964 से) औषधियों और के वर्ग के स्थान पर प्रतिस्थापित ।

वर्ग] जिनके सम्बन्ध में और वे शर्तें, परिसीमाएं या निर्बन्धन जिनके अधधीन ऐसी शक्तियों, और कर्तव्यों का प्रयोग या पालन किया जा सकेगा, विनिर्दिष्ट कर सकेंगे ;

(ण) सरकारी विश्लेषकों द्वारा दी जाने वाली रिपोर्ट के प्ररूप, और धारा 26 के अधीन परख या विश्लेषण के लिए आवेदन की रीति और उसके लिए देय फीसों विहित कर सकेंगे ;

¹[त) इस अध्याय या तदधीन बनाए गए किसी नियम के खिलाफ उन अपराधों को विनिर्दिष्ट कर सकेंगे जिनके सम्बन्ध में धारा 31 के अधीन अधिहरण का आदेश किया जा सकेगा; और]

(थ) इस अध्याय या तदधीन बनाए गए नियमों के सब या किन्हीं उपबन्धों के किसी विनिर्दिष्ट औषधि या औषधियों के वर्ग [या प्रसाधन सामग्री या प्रसाधन सामग्रियों के वर्ग] को सशर्त या अन्यथा छूट देने के लिए उपबन्ध कर सकेंगे ।

²[* * * * *]

³[33क. अध्याय का (सिद्ध सहित आयुर्वेदिक या यूनानी औषधियों को लागू न होना : इस अधिनियम में यथा अन्यथा उपबन्धित को छोड़कर, इस अध्याय की कोई बात (सिद्ध सहित) आयुर्वेदिक या यूनानी औषधियों को लागू नहीं होगी ।]

¹ 1964 के अधिनियम सं० 13 की धारा 24 द्वारा (15-9-1964 से) खण्ड (त) के स्थान पर प्रतिस्थापित ।

² 1960 के अधिनियम सं० 35 द्वारा अन्तःस्थापित उपधारा (3) को 1964 के अधिनियम सं० 13 की धारा 24 द्वारा (15-9-1964 से) लोप ।

³ 1964 के अधिनियम सं० 13 की धारा 25 द्वारा (1-2-1969 से) अन्तःस्थापित ।

(सिद्ध सहित) आयुर्वेदिक और यूनानी औषधियों से सम्बद्ध उपबन्ध

33ख. अध्याय 4क का लागू होना : यह अध्याय केवल [(सिद्ध सहित) आयुर्वेदिक और यूनानी औषधियों को लागू होगा ।

33ग. आयुर्वेदिक और यूनानी औषधि तबनीकी सलाहकार बोर्ड : (1) केन्द्रीय सरकार इस अध्याय से पैदा होने वाले तबनीकी मामलों पर केन्द्रीय सरकार और राज्य सरकारों को परामर्श देने के लिए और इस अध्याय द्वारा उसे सौंपे गए अन्य कृत्यों को करने के लिए शासकीय राजपत्र में अधिसूचना द्वारा, और ऐसी तारीख से जो उसमें विनिर्दिष्ट की जाए (आयुर्वेदिक और यूनानी औषधि तबनीकी सलाहकार बोर्ड कहलाने वाला) एक बोर्ड गठित करेगी ।

(2) बोर्ड निम्नलिखित सदस्यों से मिलकर बनेगा, अर्थात् —

- (i) स्वास्थ्य सेवा-महानिदेशक, पदेन,
- (ii) औषधि नियंत्रक, भारत, पदेन,
- (iii) स्वास्थ्य मंत्रालय का स्वदेशी चिकित्सा पद्धति सलाहकार, पदेन,
- (iv) केन्द्रीय औषधि प्रयोगशाला निदेशक, कलकत्ता, पदेन,
- (v) धारा 33च के अधीन सरकारी विश्लेषक का पद धारण करने वाला एक व्यक्ति जो केन्द्रीय सरकार द्वारा नामनिर्देशित किया जाएगा,
- (vi) केन्द्रीय सरकार द्वारा नामनिर्देशित किया जाने वाला एक भेषज अभिज्ञानी,
- (vii) केन्द्रीय सरकार द्वारा नामनिर्देशित किया जाने वाला एक फाइटोरसायनज्ञ,
- (viii) केन्द्रीय आयुर्वेदिक अनुसंधान परिषद् के सदस्यों में से केन्द्रीय सरकार द्वारा नामनिर्देशित किए जाने वाले दो व्यक्ति,
- (ix) द्रव्य गुण और भेषज कल्पना का एक शिक्षक जो केन्द्रीय सरकार द्वारा नामनिर्देशित किया जाएगा,
- (x) इलमुल अदविय : और तकलीसवा दवासाजी का एक शिक्षक जो केन्द्रीय सरकार द्वारा नामनिर्देशित किया जाएगा,
- (xi) केन्द्रीय सरकार द्वारा नामनिर्देशित किए जाने वाले दो व्यक्ति जिनमें (सिद्ध सहित) आयुर्वेदिक और यूनानी औषधि उद्योग में से प्रत्येक का प्रतिनिधित्व करने के लिए एक-एक व्यक्ति होगा,

(1) 1954 के अधिनियम सं० 13 की धारा 26 द्वारा (1-2-1969 से) अन्तः स्थापित ।

(xii) केन्द्रीय सरकार द्वारा नामनिर्देशित किए जाने वाले दो व्यक्ति जिनके (सिद्ध सहित) आयुर्वेदिक और यूनानी औषधि प्रणालियों के व्यवसायियों में से प्रत्येक का एक-एक व्यक्ति होगा।

(3) केन्द्रीय सरकार बोर्ड के एक सदस्य को उसका अध्यक्ष नियुक्त करेगी।

(4) बोर्ड के नामनिर्देशित सदस्य अपना पद तीन वर्ष तक धारण करेंगे किन्तु पुनर्नामनिर्देशन के लिए पात्र होंगे।

(5) केन्द्रीय सरकार के पूर्व अनुमोदन के अधीन रहते हुए बोर्ड, अपनी गणपूर्ति नियत करने वाली और अपनी प्रक्रिया और अपने द्वारा किए जाने वाले सब काम-काज का संचालन विनियमित करने वाली उपविधियां बना सकेगा।

(6) बोर्ड में किसी रिक्तता के होते हुए भी उसके कृत्य किए जा सकेंगे।

(7) केन्द्रीय सरकार किसी व्यक्ति को बोर्ड का सचिव नियुक्त करेगी और बोर्ड के लिए ऐसे लिपिकीय और अन्य कर्मचारिवृन्द उपलब्ध करेगी जैसे केन्द्रीय सरकार आवश्यक समझती है।

33व. (सिद्ध सहित) आयुर्वेदिक और यूनानी औषधियों के विक्रयार्थ विनिर्माण का प्रतिषेध : उस तारीख से जो केन्द्रीय सरकार द्वारा शासकीय राजपत्र में अधिसूचना द्वारा इस निमित्त नियत की जाए कोई व्यक्ति स्वयम् या अपनी ओर से किसी अन्य व्यक्ति द्वारा किसी (सिद्ध सहित) आयुर्वेदिक या यूनानी औषधि का विक्रयार्थ विनिर्माण —

- (क) विहित स्वास्थ्यकर परिस्थितियों के अधीन करने के सिवाय नहीं करेगा ;
- (ख) विहित अर्हताओं वाले व्यक्ति के पर्यवेक्षण के अधीन करने के सिवाय नहीं करेगा ;
- (ग) इस अध्याय के अधीन ऐसे प्रयोजन के लिए दी गई अनुज्ञप्ति की शर्तों के अधीन और अनुसार करने के सिवाय नहीं करेगा ;
- (घ) उस दशा के सिवाय नहीं करेगा जिसमें ऐसी औषधि की तैयारी में प्रयुक्त कच्ची सामग्रियां असली हैं और उचित रूप से पहचान ली गई हैं ;
- (ङ) उस दशा के सिवाय नहीं करेगा जिसमें उस औषधि पर उसमें अन्तर्विष्ट सब संघटकों को सही सूची और ऐसी अन्य विशिष्टियों का जो विहित की जाएं लेबल लगा हुआ है ; और
- (च) इस अध्याय और तदधीन बनाए गए किसी नियम के उपबन्धों में से किसी के उल्लंघन में नहीं करेगा :

परन्तु इस धारा की कोई बात उन वैद्यों और हकीमों पर लागू नहीं होगी जो ऐसी औषधियों का विनिर्माण अपने चिकित्साधीन व्यक्तियों के उपयोग के लिए करते हैं :

परन्तु यह और कि खण्ड (क), (ख) और (ग) की कोई बात परीक्षा, परख या विश्लेषण के प्रयोजन के लिए किसी ऐसी औषधि के विहित शर्तों के अध्याधीन थोड़े परिमाण में विनिर्माण को लागू नहीं होगी।

33इ. (सिद्ध सहित) आयुर्वेदिक और यूनानी औषधियों के विक्रय आदि पर निर्बंधन : उस तारीख से जो राज्य सरकार द्वारा शासकीय राजपत्र में अधिसूचना द्वारा इस निमित्त नियत की जाए, कोई व्यक्ति स्वयम् या अपनी ओर से किसी अन्य व्यक्ति द्वारा किसी ऐसे (सिद्ध सहित) आयुर्वेदिक या यूनानी औषधि का, जो इस अध्याय के अधीन, अनुज्ञप्त विनिर्माता द्वारा विनिर्मित औषधि से भिन्न है, विक्रय नहीं करेगा या उसे विक्रयार्थ स्टॉक में नहीं रखेगा या अभिदर्शित नहीं करेगा अथवा वितरित नहीं करेगा।

33च. सरकारी विश्लेषक : (1) केन्द्रीय सरकार या राज्य सरकार, शासकीय राजपत्र में अधिसूचना द्वारा, विहित अर्हताओं वाले ऐसे व्यक्तियों को, जिन्हें वह ठीक समझती है, ऐसे क्षेत्रों के लिए सरकारी विश्लेषक नियुक्त कर सकेगी जैसे यथास्थिति केन्द्रीय सरकार या राज्य सरकार द्वारा उन्हें सौंपे जाएं।

(2) उपधारा (1) में किसी बात के होते हुए भी न तो केन्द्रीय सरकार और न राज्य सरकार ही किसी ऐसे अधिकारी को जो उसके अधीन सेवा न कर रहा हो उस सरकार की, जिसके अधीन वह सेवा कर रहा हो, पूर्व सम्मति के बिना सरकारी विश्लेषक के रूप में नियुक्त करेगी।

33छ. निरीक्षक : (1) केन्द्रीय सरकार या राज्य सरकार, शासकीय राजपत्र में अधिसूचना द्वारा, विहित अर्हताओं वाले ऐसे व्यक्तियों को जिन्हें वह ठीक समझती है ऐसे क्षेत्रों के लिए निरीक्षक नियुक्त कर सकेगी जो उन्हें, यथास्थिति, केन्द्रीय सरकार या राज्य सरकार द्वारा सौंपे जाएं।

(2) शक्तियां जो निरीक्षक द्वारा प्रयुक्त की जा सकेंगी और कर्तव्य जिनका उस द्वारा पालन किया जा सकेगा, तथा वे शर्तें, परिसीमाएं या निर्बंधन जिनके अधीन ऐसी शक्तियों और कर्तव्यों का प्रयोग या पालन किया जा सकेगा ऐसे होंगे जैसे विहित किए जाएं।

(3) इस धारा के अधीन किसी भी ऐसे व्यक्ति को निरीक्षक नियुक्त नहीं किया जाएगा जिसका किसी औषधि के विनिर्माण या विक्रय में कोई वित्तीय हित हो।

(4) प्रत्येक निरीक्षक भारतीय दण्ड संहिता की धारा 21 (1860 का 45) के अर्थ में लोक सेवक समझा जाएगा और ऐसे प्राधिकारी का शासकीय रूप से अधीनस्थ होगा जिसे नियुक्त करने वाली सरकार इस निमित्त विनिर्दिष्ट करे।

33ज. धारा 22, 23, 24 और 25 के उपबन्धों का लागू होना : धारा 22, 23, 24 और 25 के उपबन्ध और तदधीन बनाए गए नियम, यदि कोई हों, इस अध्याय के अधीन नियुक्त निरीक्षक और सरकारी विश्लेषक के सम्बन्ध में इस उपान्तर के अधीन कि उक्त धाराओं में "औषधि" के प्रति निर्देशों का यह अर्थ किया जाएगा कि वे "(सिद्ध सहित) आयुर्वेदिक या यूनानी औषधि" के प्रति निर्देश हैं, यावत् शक्य वैसे ही लागू होंगे जैसे वे अध्याय 4 के अधीन नियुक्त निरीक्षक और सरकारी विश्लेषक के सम्बन्ध में लागू होते हैं।

33अ. इस अध्याय के उल्लंघन में (सिद्ध सहित) आयुर्वेदिक और यूनानी औषधियों के विनिर्माण, विक्रय आदि के लिए शास्ति : जो कोई धारा 33ड या धारा 33ड या धारा 33ज द्वारा यथा लागू धारा 24 के उपबन्धों या इस अध्याय के अधीन बनाए गए किसी नियम का उल्लंघन करेगा वह कारावास से, जिसकी अवधि तीन मास तक की हो सकेगी, या जुर्माने से, जो पांच सौ रुपए तक का हो सकेगा, अथवा दोनों से दण्डनीय होगा।

33ज. पश्चात्तर्वर्ती अपराधों के लिए शास्ति : जो कोई धारा 33घ या धारा 33ड के अधीन अपराध का सिद्ध दोष होने पर उक्त धारा के अधीन अपराध का पुनः सिद्धदोष होगा वह कारावास से, जिसकी अवधि छह मास तक की हो सकेगी, या जुर्माने से, जो एक हजार रुपए तक का हो सकेगा, अथवा दोनों से दण्डनीय होगा।

33ट. अधिहरण : जहां कोई व्यक्ति इस अध्याय के अधीन सिद्धदोष किया गया है वहां उस (सिद्ध सहित) आयुर्वेदिक या यूनानी औषधी का स्टॉक जिसके सम्बन्ध में उल्लंघन हुआ है अधिहरणीय होगा।

33ठ. सरकारी विभागों को उपबन्धों का लागू होना : धारा 33ट में अन्तर्विष्ट उपबन्धों के सिवाय इस अध्याय के उपबन्ध किसी सरकारी विभाग द्वारा किसी (सिद्ध सहित) आयुर्वेदिक या यूनानी औषधि के विक्रयार्थ विनिर्माण, विक्रय या वितरण के सम्बन्ध में उल्लंघन वैसे ही लागू होंगे जैसे वे किसी अन्य व्यक्ति द्वारा ऐसी औषधि के विक्रयार्थ विनिर्माण, विक्रय या वितरण के सम्बन्ध में लागू होते हैं।

33ड. अपराधों का संज्ञान : (1) इस अध्याय के अधीन कोई अभियोजन निरीक्षक द्वारा संस्थित किए जाने के सिवाय नहीं किया जाएगा।

(2) प्रेसिडेंसी मजिस्ट्रेट या प्रथम वर्ग के मजिस्ट्रेट से अवर कोई न्यायालय इस अध्याय के अधीन दण्डनीय अपराध का विचारण नहीं करेगा।

33ढ. नियम बनाने की केन्द्रीय सरकार की शक्ति : (1) केन्द्रीय सरकार बोर्ड के साथ परामर्श करने के पश्चात् और शासकीय राजपत्र में अधिसूचना द्वारा पूर्व प्रकाशन के पश्चात्, इस अध्याय के उपबन्धों को प्रभावी करने के प्रयोजन के लिए नियम बना सकेगी :

परन्तु यदि केन्द्रीय सरकार की यह राय हो कि ऐसी परिस्थितियां पैदा हो गई हैं, जिनसे आवश्यक हो गया है कि बोर्ड के साथ ऐसे परामर्श के बिना नियम बना लिए जाएं तो बोर्ड के साथ परामर्श अभिमोचित किया जा सकेगा, किन्तु ऐसी दशा में नियम बना लेने के छह मास के अन्दर बोर्ड से परामर्श किया जाएगा और केन्द्रीय सरकार किन्हीं भी ऐसे सुझावों पर, जो बोर्ड उक्त नियमों के संशोधन के सम्बन्ध में दे, विचार करेगी।

(2) पूर्वगामी शक्ति की व्यापकता पर प्रतिकूल प्रभाव डाले बिना ऐसे नियम —

(क) (सिद्ध सहित) आयुर्वेदिक या यूनानी औषधियों की परख और विश्लेषण के लिए प्रयोगशालाओं की स्थापना के वास्ते उपबन्ध कर सकेंगे ;

- (ख) सरकारी विश्लेषकों की अहंताएं और कर्तव्य तथा निरीक्षकों की अहंताएं विहित कर सकेंगे ;
- (ग) यह अवधारण करने में की जाने वाली परख या विश्लेषण के ढंग विहित कर सकेंगे कि क्या किसी (सिद्ध सहित) आयुर्वेदिक या यूनानी औषधि पर उन संघटकों की सही सूची का लेबल लगा हुआ है जिनका उसमें अन्तर्दिष्ट होना तात्पर्यित है ;
- (घ) किसी पदार्थ को विपैले पदार्थ के रूप में विनिर्दिष्ट कर सकेंगे ;
- (ङ) (सिद्ध सहित) आयुर्वेदिक या यूनानी औषधियों के विक्रयार्थ विनिर्माण के लिए अनुज्ञप्तियों के प्ररूप, ऐसी अनुज्ञप्तियों के लिए आवेदनों का प्ररूप वे शर्तें जिनके अधीन ऐसी अनुज्ञप्तियां दी जा सकेंगी उनको देने के लिए सशक्त प्राधिकारी और उनके लिए देय फीस विहित कर सकेंगे ;
- (च) पैक की गई (सिद्ध सहित) आयुर्वेदिक या यूनानी औषधियों पर लेबल लगाने का तरीका विनियमित कर सकेंगे और वे बातें विहित कर सकेंगे जो ऐसे लेबलों में हो सकेंगी या नहीं हो सकेंगी ;
- (छ) ऐसी शर्तों को विहित कर सकेंगे जिनके अधीन (सिद्ध सहित) आयुर्वेदिक या यूनानी औषधियों को परीक्षा, परख या विश्लेषण के प्रयोजन के लिए थोड़े परिमाण में विनिर्मित किया जा सकेंगा ; और
- (ज) कोई अन्य विषय विहित कर सकेंगे जो इस अध्याय के अधीन विहित किया जाना है या किया जाए ।

33ण. प्रथम अनुसूची को संशोधित करने की शक्ति : केन्द्रीय सरकार, इस अध्याय के प्रयोजनों के लिए प्रथम अनुसूची में परिवर्धन या अन्यथा संशोधन बोर्ड से परामर्श करने के पश्चात् और वैसा करने के अपने आशय की तीन मास से अग्यून की सूचना शासकीय राजपत्र में अधिसूचना द्वारा देकर वैसी ही अधिसूचना द्वारा कर सकेंगी और तब उक्त अनुसूची तदनुकूल संशोधित समझी जाएगी ।]

1[अध्याय 5

प्रकीर्ण

²[³[33अ] निदेश देने की शक्ति : केन्द्रीय सरकार किसी राज्य सरकार को ऐसे निदेश दे सकेगी जैसे इस अधिनियम के या तदधीन बनाए गए किसी नियम या आदेश के उपबन्धों में से किसी का उस राज्य में निष्पादन करने के लिए केन्द्रीय सरकार को आवश्यक प्रतीत हों।]

34. कम्पनियों द्वारा अपराध: (1) यदि इस अधिनियम के अधीन कोई अपराध किसी कम्पनी द्वारा किया गया हो तो प्रत्येक व्यक्ति जो उस अपराध के किए जाने के समय उस कम्पनी के कारबार के संचालन के लिए उस कम्पनी का भारसाधक और उसके प्रति उत्तरदायी था और साथ ही वह कम्पनी भी उस अपराध के दोषी समझे जाएंगे तथा तदनुसार अपने विरुद्ध कार्यवाही किए जाने और दण्डित किए जाने के भागी होंगे:

परन्तु इस उपधारा की कोई बात किसी ऐसे व्यक्ति को दण्ड का भागी नहीं बनाएगी यदि वह यह साबित कर दे कि अपराध उसकी जानकारी के बिना किया गया था या उसने ऐसा अपराध किया जाना निवारित करने के लिए सब सम्यक् तत्परता बरती थी।

(2) उपधारा (1) में किसी बात के होते हुए भी, जहां इस अधिनियम के अधीन कोई अपराध किसी कम्पनी द्वारा किया गया हो तथा यह साबित हो कि वह अपराध कम्पनी के किसी निदेशक, प्रबन्धक, सचिव या अन्य अधिकारी की सम्मति या मौनानुकूलता से किया गया है या उसकी किसी उपेक्षा के कारण हुआ माना जा सकता है, वहां ऐसा निदेशक, प्रबन्धक, सचिव या अन्य अधिकारी भी उस अपराध का दोषी समझा जाएगा तथा तदनुसार अपने विरुद्ध कार्यवाही किए जाने और दण्डित किए जाने का भागी होगा।

स्पष्टीकरण—इस धारा के प्रयोजनों के लिए —

(क) “कम्पनी” से कोई निगमित निकाय अभिप्रेत है और इसके अन्तर्गत फर्म या व्यष्टियों का अन्य संगम भी है; तथा

(ख) फर्म के सम्बन्ध में “निदेशक” से उस फर्म का भागीदार अभिप्रेत है।

⁴[34क. सरकारी विभागों द्वारा अपराध : जहां अध्याय 4 या अध्याय 4 क के अधीन कोई अपराध सरकार के किसी विभाग द्वारा किया गया है वहां ऐसा प्राधिकारी जो

(1) 1955 के अधिनियम सं० 11 की धारा (16 द्वारा 34) प्रतिस्थापित।

(2) 1960 के अधिनियम सं० 37 की धारा 17 द्वारा (16-3-1961 से) अन्तःस्थापित।

(3) 1964 के अधिनियम सं० 13 की धारा 27 द्वारा (15-9-1964 से) धारा 35क की धारा 33ण के रूप में पुनर्संख्याकित किया गया।

(4) 1964 के अधिनियम सं० 13 की धारा 28 द्वारा (15-9-1969 से) अन्तःस्थापित।

अधीनस्थों के विनिर्माण, विक्रय या वितरण का भारसाधक केन्द्रीय सरकार द्वारा विनिर्दिष्ट किया गया है या जहाँ ऐसा कोई प्राधिकारी विनिर्दिष्ट नहीं है वहाँ उस विभाग का अध्यक्ष उस अपराध का दोषी समझा जाएगा तथा तदनुसार अपने विरुद्ध कार्यवाही किए जाने और दण्डित किए जाने का भागी होगा :

परन्तु इस धारा की कोई बात किसी ऐसे प्राधिकारी या व्यक्ति को यथास्थिति अध्याय 4 या अध्याय 4क में उपबंधित दण्ड का भागी नहीं बनाएगी यदि ऐसा प्राधिकारी या व्यक्ति यह साबित कर दे कि अपराध उसकी जानकारी के बिना किया गया था या ऐसे प्राधिकारी या व्यक्ति ने ऐसे अपराध का किया जाना निवारित करने के लिए सब सम्यक् तत्परता बरती थी ।]

35. इस अधिनियम के अधीन पारित दण्डादेशों का प्रकाशन : (1) यदि कोई व्यक्ति इस अधिनियम के अधीन किसी अपराध का सिद्ध दोष होता है तो उस न्यायालय के लिए जिसके समक्ष दोषसिद्धि होती है यह विधिपूर्ण होगा कि वह अपराधी के नाम, निवास स्थान, अपराध जिसका वह सिद्धदोष हुआ है और शास्ति को, जो उस पर लगाई गई है, ऐसे व्यक्ति के व्यय पर ऐसे समाचारपत्रों में और ऐसी अन्य रीति में प्रकाशित कराए जैसी वह न्यायालय निदिष्ट करे ।

(2) ऐसे प्रकाशन के व्यय दोषसिद्धि से सम्बद्ध खर्च का भाग समझे जाएंगे और उसी रीति से वसूलीय होंगे जिससे वे खर्चे वसूलीय होते हैं ।

36. वर्धित शास्तियां अधिरोपित करने की मजिस्ट्रेट की शक्ति : दण्ड प्रक्रिया संहिता, 1898 (1898 का 5) में किसी बात के होते हुए भी, ¹[****] किसी प्रेसिडेंसी मजिस्ट्रेट या किसी प्रथम वर्ग के मजिस्ट्रेट के लिए यह विधिपूर्ण होगा कि वह इस अधिनियम द्वारा प्राधिकृत कोई भी दण्ड पारित करे जो उक्त संहिता के अधीन ¹[****] उसकी शक्तियों से अधिक हो ।

37. सद्भावपूर्वक की गई कार्रवाई के लिए परित्राण : कोई भी वाद, अभियोजन या अन्य विधिक कार्यवाही किसी भी ऐसी बात के बारे में जो इस अधिनियम के अधीन सद्भावपूर्वक की गई हो या की जाने के लिए आशयित हो किसी भी व्यक्ति के विरुद्ध न होगी ।]

²[38. नियमों का संसद के समक्ष रखा जाना : इस अधिनियम के अधीन बनाया गया प्रत्येक नियम, बनाए जाने के पश्चात् यथाशक्य शीघ्र, संसद के प्रत्येक सदन

(1) यथोक्त की धारा 29 द्वारा (15-9-1964 से) धारा 32 का शब्दों और अंकों का लोप ।

(2) 1964 के अधिनियम सं० 13 की धारा 30 द्वारा (15-9-1964 से) अन्तःस्थापित ।

के समक्ष, उस समय जब वह सत्र में हो, कुल मिलाकर तीस दिन की कालावधि के लिए, जो एक सत्र में या दो क्रमवर्ती सत्रों में समाविष्ट हो सकेगी, रखा जाएगा और यदि उस सत्र के, जिसमें वह ऐसे रखा गया हो, या ठीक बाद के सत्र के अवसान के पूर्व दोनों सदन उस नियम में कोई उपान्तर करने के लिए सहमत हो जाएं या दोनों सदन सहमत हो जाएं कि वह नियम नहीं बनाया जाना चाहिए तो तत्पश्चात्, यथास्थिति, वह नियम, ऐसे उपान्तरित रूप में ही प्रभावी होगा या उसका कोई भी प्रभाव न होगा, किन्तु इस प्रकार कि ऐसा कोई उपान्तर या बातिलकरण उस नियम के अधीन पहले की गई किसी बात की विधिमान्यता पर प्रतिकूल प्रभाव डाले बिना होगा।

¹ [प्रथम अनुसूची]

(धारा 3क देखिए)

क--(सिद्ध सहित) आयुर्वेदिक प्रणाली

क्रम सं०	पुस्तक का नाम	क्रम सं०	पुस्तक का नाम
आयुर्वेद			
1	आरोग्य कल्पद्रुम	26	रसेन्द्र सार संग्रह
2	अर्क प्रकाश	27	रस प्रदीपिका
3	आर्य भिषक	28	सहस्रयोग
4	अष्टांग हृदय	29	सर्वरोग चिकित्सा रत्नम्
5	अष्टांग संग्रह	30	सर्वयोग चिकित्सा रत्नम्
6	आयुर्वेद कल्पद्रुम	31	शारंगधर संहिता
7	आयुर्वेद प्रकाश	32	सिद्ध भेषज्य मणिमाला
8	आयुर्वेद संग्रह	33	सिद्ध योग संग्रह
9	भेषज्य रत्नावली	34	सुश्रुत संहिता
10	भारत भेषज्य रत्नाकर	35	वैद्य चिन्तामणि
11	भाव प्रकाश	36	वैद्यक शब्द सिन्धु
12	बृहत् निघंटु रत्नाकर	37	वैद्यक चिकित्सा सार
13	चरक संहिता	38	वैद्य जीवन
14	चरक दत्त	39	वासव राजीयम
15	गड़ निग्रह	40	योग रत्नाकर
16	कूपी पाक्व रसायन	41	योग तरंगिणी
17	निघंटु रत्नाकर	42	योग चिन्तामणि
18	रस चंदांशु	43	कश्यप संहिता
19	रस राज सुन्दर	44	भेल संहिता
20	रस रत्न समुच्चय	45	विश्वनाथ चिकित्सा
21	रसतंत्र सार सिद्ध प्रयोग संग्रह	46	ब्रिन्द चिकित्सा
22	रस तरंगिणी	47	आयुर्वेद चिन्तामणि
23	रस योग सागर	48	अभिनव चिन्तामणि
24	रस योग रत्नाकर	49	आयुर्वेद-रत्नाकर
25	रस योग संग्रह	50	योगरत्न संग्रह

(¹) 1964 के अधिनियम सं० 13 की धारा 31 द्वारा अनुसूची प्रतिस्थापित ।

प्रथम अनुसूची 1-2-1969 से और द्वितीय अनुसूची 15-9-1964 से प्रवृत्त ।

क्रम सं० पुस्तक का नाम

क्रम सं० पुस्तक का नाम

51 रसमित्र

53 रसमंजरी

52 द्रव्यगुणनिघंटु

54 वंग सेन

सिद्ध

55 सिद्ध वैद्य तिरिट्टु

70 अगस्तियर कन्म सुत्तिरम्

56 तेरियर महा करिसल

71 18 सिद्धर का चिल्लरै कौवे

57 बह्य मुनि करुक्कडे (300)

72 योगि वात काव्यम्

58 भोगर (700)

73 तेरियर तरु

59 पुलिप्पणि (500)

74 अगस्तियर वैद्य काव्यम् (1500)

60 अगस्तियर परिपुराणम् 400

75 बाल बगडम

61 तेरियर यामगम्

76 चिमिट्टू रत्न (रत्न) चुरुक्कम्

62 अगस्तियर चेन्दुरम् (300)

77 नागमुनि (200)

63 अगस्तियर (1500)

78 अगस्तियर चिल्लरै कौवे

64 आत्मरक्षामृतम्

79 चिकिच्चा रत्न दीपम्

65 अगस्तियर पिन (80)

80 अगस्तियर नयन विभि

66 अगस्तियर रत्न चुरुक्कम्

81 युगि करिसल (151)

67 तेरियर करिसल (300)

82 अगस्तियर वल्लति (600)

68 वीरमामुनि नास कण्डम

83 तेरियर तैल वर्कम्

69 अगस्तियर (600)

ख—यूनानी (तिब्ब) प्रणाली

1 कराबादीन कादरी

7 कराबादीन जदीद

2 कराबादीन कबीर

8 किताबुल तकलीस

3 कराबादीन आजम

9 सनत उल तकलीस

4 इलाज उल अमराज

10 मिपता उल खजाएन

5 अल कराबादीन

11 मदानुल अक्सीर

6 ब्याज कबीर द० 2

12 मखजनुल मुरब्बात

द्वितीय अनुसूची

(धारा 8 और 16 देखिए)

आयात औषधियों द्वारा और विक्रयार्थ विनिर्मित, विक्रीत, विक्रयार्थ स्टॉक में रखे गए या प्रदर्शित अथवा वितरित औषधियों द्वारा अनुवर्तन किए जाने वाले मानक

औषधि का वर्ग	अनुवर्तन किया जाने वाला मानक
(1)	(2)
1. पेटेन्ट या साम्प्रतिक औषधियां जो होम्यो-पैथी औषधियों से भिन्न हों।	लेबल या आधान पर विहित रीति में सम्प्रदर्शित फारमूला या संघटकों की सूची तथा ऐसे अन्य मानक जो विहित किए जाएं।
2. साधारणतया वैक्सीन, सीरा टॉक्सिन, टॉक्साइड, टॉक्सिन रोधी और एण्टिजन के रूप में ज्ञात पदार्थ और इस प्रकार के जैव उत्पाद।	इन्टरनेशनल लेबोरेटरी फार बायोलॉजिकल स्टैंडर्ड्स, स्टैंडैन्स, सीरम इंस्टीट्यूट, कोपनहेगन में अनुरक्षित मानक और शक्ति, क्वालिटी और शुद्धता के ऐसे अतिरिक्त मानक जैसे विहित किए जाएं।
3. विटामिन, हार्मोन और सदृश उत्पाद।	इन्टरनेशनल लेबोरेटरी फार बायोलॉजिकल स्टैंडर्ड्स, नेशनल इंस्टीट्यूट फार मेडिकल रीसर्च, लन्दन में अनुरक्षित मानक और शक्ति, क्वालिटी और शुद्धता के ऐसे अतिरिक्त मानक जैसे विहित किए जाएं।
4. (खाद्य से भिन्न) ऐसे पदार्थ जो मानव शरीर की रचना या किसी क्रिया को प्रभावित करने के लिए आशयित हैं या ऐसे पीढ़क जन्तुओं या कीटों को जो मनुष्यों या पशुओं में रोग पैदा करते हैं नष्ट करने के लिए प्रयुक्त किए जाने के वास्ते आशक्ति हैं।	ऐसे मानक जो विहित किए जाएं।

¹[4—क होमियोपैथिक औषधि

(क) भारतीय होमियोपैथिक भेषज कोष में सम्मिलित औषधि

भारतीय होमियोपैथिक भेषज कोष के संस्करण में विनिर्दिष्ट तदुपता, शुद्धता

(1)

(2)

(ख) ऐसी औषध जो भारतीय होमियोपैथिक भेषजकोष में सम्मिलित नहीं है किन्तु जो संयुक्त राज्य अमेरिका या यूनाइटेड किंगडम के होमियोपैथिक भेषजकोष या जर्मन होमियोपैथिक भेषजकोष में सम्मिलित है।

(ग) ऐसी औषध जो भारतीय या संयुक्त राज्य अमेरिका या यूनाइटेड किंगडम के होमियोपैथिक भेषजकोष या जर्मन होमियोपैथिक भेषजकोष में सम्मिलित नहीं है।

2[5-अन्य औषधियां

(क) भारतीय औषधकोष में दी हुई पहचान, शुद्धता और शक्ति के मानक, जो तत्समय प्रवृत्त भारतीय औषधकोष के संस्करण में विनिर्दिष्ट हैं, और ऐसे अन्य मानक जैसे विहित किए जाएं। यदि औषधियों की पहचान, शुद्धता और शक्ति के मानक तत्समय प्रवृत्त भारतीय औषध कोष के संस्करण में विनिर्दिष्ट नहीं हैं किन्तु तत्काल पूर्ववर्ती भारतीय औषधकोष के संस्करण में विनिर्दिष्ट हैं तो पहचान, शुद्धता और शक्ति के मानक वे होंगे जो भारतीय औषधकोष के उस तत्काल पूर्ववर्ती संस्करण में दिए गए हैं, तथा ऐसे अन्य मानक होंगे जैसे विहित किए जाएं।

(ख) औषधियां जो भारतीय औषध कोष में नहीं दी गई हैं किन्तु किसी अन्य देश के किसी औषधकोष में दी गई हैं।

और सामर्थ्य के उस समय के मानक और यथा विहित कोई अन्य मानक।

ऐसे भेषजकोष के संस्करण, जिसमें औषध के लिए विनिर्दिष्ट तदूपता, शुद्धता और सामर्थ्य दी गई है, उस तदूपता, और शुद्ध सामर्थ्य के उस समय के मानक और यथाविहित कोई अन्य मानक।

पत्र के लेबल पर विहित रीति से दाशत घटकों का सूत्राया सूची और केन्द्रीय सरकार द्वारा यथाविहित कोई अन्य मानक।

पहचान, शुद्धता और शक्ति के मानक, जो किसी अन्य देश के तत्समय प्रवृत्त ऐसे शासकीय औषधकोष के संस्करण में उन औषधियों के लिए विनिर्दिष्ट हैं, और ऐसे

अन्य मानक जैसे विहित किए जाएं। यदि औषधियों की पहचान, शुद्धता और शक्ति के मानक तत्समय प्रवृत्त उस शासकीय औषधकोष के संस्करण में विनिर्दिष्ट नहीं हैं किन्तु तत्काल पूर्ववर्ती संस्करण में विनिर्दिष्ट हैं तो पहचान, शुद्धता और शक्ति के मानक वे होंगे जो उस शासकीय औषधकोष की उस तत्काल पूर्ववर्ती संस्करण में दिए गए हैं, तथा ऐसे अन्य मान होंगे जैसे विहित किए जाएं।

1. साधारण कानूनी नियम सं० 820 दिनांक 24-6-1978 द्वारा अन्तः स्थापित भारत के राजपत्र भाग 2 खण्ड 3(2), पृ० 1471।
2. साधारण कानूनी नियम आदेश सं० 835 दिनांक 18-8-1973, भारत के राजपत्र भाग 2 खण्ड 3(1) द्वारा प्रतिस्थापित।

THE DRUGS AND COSMETICS RULES, 1945

(Under the Drugs and Cosmetics Act, 1940)

DEPARTMENT OF HEALTH
NOTIFICATION

New Delhi, the 21st December 1945

No. F. 28-10/45-H(1).—In exercise of the powers conferred by Sections 6(2), 12 and 33 of the Drugs and Cosmetics Act, 1940 (XXIII of 1940) the Central Government is pleased to make the following Rules :—

RULES

PART I—PRELIMINARY

1. *Short title, extent and commencement.*—(1) These Rules may be called the Drugs and Cosmetics Rules, 1945.

** (2) They extend to the whole of India.

2. *Definitions.*—In these Rules, unless there is anything repugnant in the subject or context—

(a) “the Act” means the Drugs and Cosmetics Act, 1940 (XXIII of 1940) as amended from time to time;

@ (b)

(c) “Director” means the Director of the Central Drugs Laboratory;

(d) “Form” means a form set forth in Schedule A;

*(dd) Homoeopathic medicines include any drug which is recorded in Homoeopathic provings or therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative Homoeopathic literature of India and abroad and which is prepared according to the techniques of Homoeopathic pharmacy and covers combination of ingredients of such Homoeopathic medicines but does not include a medicine which is administered by parenteral route.

(e) “Laboratory” means the Central Drugs Laboratory;

†(ee) Registered Medical Practitioner means a person—

(i) holding a qualification granted by an authority specified or notified under section 3 of the Indian Medical Degrees Act, 1916 (7 of 1916), or specified in the Schedules to the Indian Medical Council Act, 1956 (102 of 1956); or

*Added under Government of India Notification No. F. 1-59/68-D, dated 19th Nov. 1969.

†Added by Government of India, Notification No. F. 1-22/59-D, dated 9th April, 1960.

**Amended by G. S. R. 358 dated 15-3-1975 (Govt. of India Notification No. X 11011/3/72-D & MS dated 5-3-1975).

@ Deleted under GSR No. 19..... dt..... 7-1-78.... (Govt. of India Notification No. X. 11013/1/77-D & MS dated 15-12-1977.

- (ii) registered or eligible for registration in a medical register of a State meant for the registration of persons practising the modern scientific system of medicine **excluding the Homoeopathic system of medicine; or
- (iii) registered in a medical register,** other than a register for the registration of Homoeopathic practitioner, of a State, who although not falling within sub-clause (i) or sub-clause (ii) is declared by a general or special order made by the State Government in this behalf as a person practising the modern scientific system of medicine for the purposes of this Act; or
- (iv) registered or eligible for registration in the register of dentists for a State under the Dentists Act, 1948 (16 of 1948); or
- (v) who is engaged in the practice of veterinary medicine and who possesses qualifications approved by the State Government.

*(f) 'retail sale' means a sale other than a sale by way of wholesale dealing;

†(g) 'sale by way of wholesale dealing' means sale to a person for the purpose of selling again and includes sale to a hospital, dispensary, medical, educational or research institution.

‡(h) "Schedule" means a Schedule to these Rules.

†(i) State Government in relation to a Union Territory means the Administrator thereof.

(j) 'Poisonous substance' means a substance specified in Schedule E.

PART II—THE CENTRAL DRUGS LABORATORY

3. *Functions.*—It shall be the function of the Laboratory—

- (i) to analyse or test such samples of drugs as may be sent to it under sub-section (2) of Section 11, or under sub-section (4) of Section 25 of the Act;

†(ii)

*Amended or added under Government of India Notification No. F. 1-3/51-DS., Dated 15th October, 1954.

†Amended or omitted by Government of India Notification No. F-1-16/57-D, dated 15th June, 1957.

‡Amended by Government of India Notification No. F. 28-10/45-H (1), dated 31st March 1957.

**Amended by S. O. No. 2139 dated 12-8-1972 (Govt. of India Notification No. X. 11014/12/72-D, dated the 5th June, 1972).

- (iii) to carry out such other duties as may be entrusted to it by the Central Government or, with the permission of the Central Government, by a State Government after consultation with the Drugs Technical Advisory Board.

*3A(1) The functions of the Laboratory in respect of the following drugs or classes of drugs shall be carried out at the Central Research Institute, Kasauli, and the functions of the Director in respect of the said drugs or classes of drugs shall be exercised by the Director of the said Institute :—

- (1) Sera
- (2) Solution of serum proteins intended for injection
- (3) Vaccines
- (4) Toxins
- (5) Antigens
- (6) Anti-toxins
- (7) Sterilized surgical ligature and sterilized surgical suture.
- (8) Bacteriophages.

†(2) The functions of the Laboratory in respect of the following drugs or classes of drugs shall be carried out at the Indian Veterinary Research Institute, Izatnagar or Mukteshwar and the functions of the Director in respect of the said drugs or classes of drugs shall be exercised by the Director of either of the said institutes.

- (1) Anti-sera for veterinary use.
- (2) Vaccines for veterinary use.
- (3) Toxoids for veterinary use.
- (4) Diagnostic Antigens for veterinary use.

** (3) The functions of the laboratory in respect of condoms shall be carried out at the Central Indian Pharmacopoeia Laboratory, Ghaziabad, and the functions of the Director in respect of the said condoms shall be exercised by the Director of the said Laboratory.

@ (4) The functions of the Laboratory in respect of the following drugs, shall be carried out at the National Institute of Communicable Diseases, Delhi and the functions of the Director in respect of the said drug shall be performed by the Deputy Director of the said Institute :—Oral Polio-myelitis Vaccine.

*Amended by Government of India Notification No. F. 4-1/60-D, dated 15th May, 1961.

†Amended by Govt. of India, Ministry of Health, F P&W. H. & U. D. Notification No. F.-1-6/62-D, dated the 2nd July, 1969.

**Amended by S. O. No. 2139 dated 12-8-1972 (Govt. of India Notification No. X. 11014/12/72-D, dated the 5th June, 1972).

@Added by G.S.R. No. 2655 dated 18-11-1975 (Govt. of India Notification No. X. 11014/2/74-D&MS dated 25th October, 1975).

(5) The functions of the Laboratory in respect of the following drug shall be carried out at the Laboratory of the Serologist and Chemical Examiner to the Government of India, Calcutta and the functions of the Director in respect of the said drug shall be performed by the Serologist and Chemical Examiner of the said Laboratory :—

VDRL Antigen.

4. *Despatch of samples for test or analysis.*—(1) Samples for test or analysis under sub-section (4) of Section 25 of the Act shall be sent by registered post in a sealed packet, enclosed, together with a memorandum in Form 1, in an outer cover addressed to the Director.

(2) The packet as well as the outer cover, shall be marked with a distinguishing number.

(3) A copy of the memorandum in Form 1 and a specimen impression of the seal used to seal the packet shall be sent separately by registered post to the Director.

5. *Recording of condition of seals.*—On receipt of the packet, it shall be opened by an officer authorised in writing in that behalf by the Director who shall record the condition of the seal on the packet.

6. *Report of result of test or analysis.*—After test or analysis the result of the test or analysis, together with full protocols of the tests applied, shall be supplied forthwith to the sender in Form 2.

7. *Fees.*—The fees for test and analysis shall be those specified in Schedule B.

8. *Signature of certificates.*—Certificates issued under these Rules by the Laboratory shall be signed by the Director or by an officer authorised by the Central Government by notification in the official Gazette to sign such certificates.

*PART III (Rules 9 to 20)

PART IV—IMPORT

21. In this Part—

- (a) “import licence” means a licence in Form 10 to import drugs specified in Schedules C and C(1);
- (b) “licensing authority” means the authority appointed by the Central Government to perform the duties of the licensing authority under these Rules and includes any person to whom the powers of a licensing authority may be delegated under Rule 22;
- (c) “licence for examination, test or analysis” means a licence in Form 11 to import small quantities of drugs the import of which is otherwise prohibited, for the purpose of examination, test or analysis.

*Omitted by Government of India Notification No. F. 1-16/57-D, dated 15th June, 1957.

22. The licensing authority may with the approval of the Central Government by an order in writing delegate the power to sign licences and such other powers as may be specified in the order to any other person under his control.

23. *Import licences.*—An import licence shall be required for the import of any biological or other special product specified in Schedules C or C(1).

†24. *Form and manner of application.*—(1) An application for an import licence shall be made to the licensing authority in Form 8 by the manufacturer's agent in India, and shall be accompanied by a fee of rupees fifty and by an undertaking in Form 9 signed by or on behalf of the manufacturer :

Provided that in the case of subsequent applications by the same importer for import licence for products manufactured by the same manufacturer, the fee to accompany each such application shall be rupees fifteen.

†(2) A fee of rupees twelve and fifty paise shall be paid for a duplicate copy of a licence issued under this Rule, if the original is defaced, damaged or lost.

25. *Licences for import of drugs manufactured by one manufacturer.*—(1) A single application may be made, and a single licence may be issued, in respect of the import of more than one drug or class of drugs manufactured by the same manufacturer :

*Provided that the drugs or classes of drugs are manufactured at one factory or more than one factory functioning conjointly as a single manufacturing unit;

Provided further that if a single manufacturer has two or more factories situated in different places manufacturing the same or different drugs a separate licence shall be required in respect of the drugs manufactured by each such factory.

†(2)

‡25A. *Condition to be satisfied before a licence in Form 10 is granted.*—A licence in Form 10 for the import of biological and other special products specified in Schedules C and C(1) shall not be granted unless the licensing authority is satisfied that the premises where the imported substances will be stocked by the importer are equipped with proper storage accommodation for preserving the properties of drugs to which the licence applies.

†Added or omitted under Government of India Notification No. F. 1-16/57-D, dated 15th June, 1957.

*Added under Government of India Notification No. F. 1-19/48-D, dated 27th October, 1949.

‡Added under Government of India Notification No. F. 1-9/52-D, dated 3rd November, 1958.

26. *Conditions of import licence.*—An import licence shall be subject to the following conditions :

- (i) the manufacturer shall at all times observe the undertaking given by him or on his behalf in Form 9;
- (ii) the licensee shall allow any Inspector authorized by the licensing authority in that behalf to enter with or without notice any premises where the imported substance is stocked, to inspect the means, if any, employed for testing the substance and to take samples;
- (iii) the licensee shall on request furnish to the licensing authority from every batch of each substance or from such batch or batches as the licensing authority may from time to time specify a sample of such amount as the licensing authority may consider adequate for any examination required to be made, and the licensee shall, if so required, furnish full protocols of the tests, if any, which have been applied;
- (iv) if the licensing authority so directs the licensee shall not sell or offer for sale any batch in respect of which a sample is or protocols are furnished under the last preceding subrule until a certificate authorizing the sale of the batch has been issued to him by or on behalf of the licensing authority;
- (v) the licensee shall, on being informed by the licensing authority that any part of any batch of the substance has been found by the licensing authority not to conform with the standards of strength, quality and purity prescribed by Chapter III of **the Act, or the Rules thereunder** and on being directed so to do withdraw the remainder of that batch from sale and, so far as may in the particular circumstances of the case be practicable, recall the issues already made from that batch;
- (vi) the licensee shall maintain a record of all sales by him of substances for the import of which a licence is required, showing particulars of the substance and of the person to whom sold and such further particulars, if any, as the licensing authority may specify and such record shall be open to the inspection of any Inspector authorised in that behalf by the licensing authority;
- (vii) the licensee shall comply with such further requirements, if any, applicable to the holders of import licences, as may be specified in any Rules, subsequently made under Chapter III of the Act and of which the licensing authority has given to him not less than four months' notice.

27. *Grant of import licence.*—On receipt of an application for an import licence in the form and manner prescribed in Rule 24, the licensing authority shall, on being satisfied that, if granted, the conditions of the licence will be observed, issue an import licence in Form 10.

*28. *Duration of import licence.*—A licence, unless, it is sooner suspended or cancelled, shall be valid up to the 31st December of the year following the year in which it is granted.

Provided that if application for a fresh licence is made three months before the expiry of the existing licence the current licence shall be deemed to continue in force until orders are passed on the application.

29. *Suspension and cancellation of import licence.*—If the manufacturer or licensee fails to comply with any of the conditions of an import licence, the licensing authority may after giving the manufacturer or licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, suspend or cancel it for such period as it thinks fit, either wholly or in respect of some of the substances to which it relates :

Provided that a person who is aggrieved by the suspension or cancellation of his licence may, within three months of the date of the order, appeal to the district judge of the district in which the right of appeal accrues or if there is no district judge of that district such judicial officer as the Central Government may appoint in this behalf, having jurisdiction whose decision shall be final.

30. *Prohibition of import after expiry of potency.*—No biological or other special product specified in Schedule C or C(1) shall be imported after the date shown on the label, wrapper or container of the drug as the date up to which the drug may be expected to retain a potency not less than, or not to acquire a toxicity greater than, that required, or as the case may be, permitted by the prescribed test.

†30A. (1) No new drug shall be imported except under and in accordance with the permission in writing of the licensing authority.

(2) The importer of a new drug when applying for permission shall produce before the licensing authority all documentary and other evidence, relating to its standards of quality, purity and strength and such other information as may be required by the licensing authority including the results of therapeutic trials carried out with it.

Explanation.—For the purposes of this rule, “new drug” means a drug the composition of which is such that the drug is not generally recognised among experts as safe for use under the conditions recommended or suggested in the label thereof and includes any drug the composition of which is such that the drugs, as a result of investigations for determining its safety for use under such conditions, is so recognised, but which has not, otherwise than during the course of such investigations, been used to any large extent or for any appreciable length of time under the said conditions.

*Amended by Government of India Notification No. F. 1-10/62-D, dated 19th April, 1964.

†Added under Government of India Notification No. F. 1-30/48-D, dated 14th April 1952.

30AA. *Import of New Homoeopathic medicines—*

- (1) No New Homoeopathic medicine shall be imported except under and in accordance with the permission in writing of the Licensing Authority.
- (2) The importer of a New Homoeopathic medicine when applying for permission shall produce before the Licensing Authority such documentary and other evidence as may be required by the Licensing Authority for assessing the therapeutic efficacy of the medicine including the minimum provings carried out with it.

Explanation.—For the purpose of this rule, 'New Homoeopathic medicine' means a Homoeopathic medicine which is not specified in the Homoeopathic Pharmacopoeias of the United States or the United Kingdom** or the German Homoeopathic Pharmacopoeia or which is not recognised in authoritative Homoeopathic literature as efficacious under the conditions recommended.

†30-B. *Prohibition of import of certain drugs.*—No drug, the manufacture, sale or distribution of which is prohibited in the country of origin, shall be imported under the same name or under any other name except for the purpose of examination, test or analysis.

31. *Standard for certain imported drugs.*—No biological or other special products specified in Schedule C or C(1) shall be imported unless it complies with the standard of strength, quality and purity, if any, specified in Schedule F, and the tests prescribed in that Schedule shall be applicable for determining whether any such imported drug complies with the said standards :

@Provided that in the case of biological and other special products intended for veterinary use the standards of strength, quality and purity, if any, shall be those that are specified in Schedule F(1) and the tests prescribed in that Schedule shall be applicable for determining whether any such imported drug complies with the said standards and where no standards are specified in Schedule F(1) for any veterinary drug, the standards for such drug shall be those specified in the current edition, for the time being in force, of the British Veterinary Codex.

@@32. *Packing and labelling of imported drugs.*—No drug shall be imported unless it is packed and labelled in conformity with the rules in Parts IX and X and Schedule F and further conform to the standards laid down in Part XII provided that in the case of drugs intended for veterinary use, the packing and labelling shall conform to the rules in Parts IX and X and Schedule F(1).

†Amended under Government of India Notification No. F. 1-45
4th January, 1951.

**Added under Government of India Notification No. 1-14/68-D. dt. 26-10-1968.

@Added under Govt. of India, Ministry of Health, F. P. & W. H. & U. D. Notification No. F. 1-6/62-D, dated 2-7-1969.

@@Amended by Govt. of India, Ministry of Health, F. P. & W. H. & U. D. Notification No. F. 1-6/62-D, dated 2-7-1969.

**32-A. Packing and Labelling of Homoeopathic medicine.*

No Homoeopathic medicine shall be imported unless it is packed and labelled in conformity with the rules in Part IX-A.

33. *Import of drugs for examination, test or analysis.*—Small quantities of drugs the import of which is otherwise prohibited under Section 10 of the Act may be imported for the purpose of examination, test or analysis subject to the following conditions :—

- (a) No drug shall be imported for such purpose except under a licence in Form 11;
- (b) the licensee shall use the substances imported under the licence exclusively for purposes of examination, test or analysis and shall carry on such examination, test or analysis in the place specified in the licence, or in such other places as the licensing authority may from time to time authorize;
- (c) the licensee shall allow any Inspector authorized by the licensing authority in this behalf to enter, with or without prior notice, the premises where the substances are kept, and to inspect the premises, and investigate the manner in which the substances are being used and to take samples thereof;
- (d) the licensee shall keep a record of, and shall report to the licensing authority, the substances imported under the licence, together with the quantities imported, the date of importation and the name of the manufacturer;
- (e) the licensee shall comply with such further requirements, if any applicable to the holders of licences for examination, test or analysis as may be specified in any rules subsequently made under Chapter III of the Act and of which the licensing authority has given to him not less than one month's notice.

34. *Application for licence for examination, test or analysis.*—(1) An application for a licence for examination, test or analysis shall be made in Form 12 and shall be made or countersigned by the head of the institution in which, or by a proprietor or director of the company or firm by which the examination, test or analysis will be conducted.

(2) The licensing authority may require such further particulars to be supplied as he may consider necessary.

******(3) Every application in Form 12 shall be accompanied by a fee of rupees fifteen.

35. *Cancellation of licence for examination, test or analysis.*—(1) A licence for examination, test or analysis may be cancelled by the licensing authority for breach of any of the conditions subject to which the licence was issued.

(2) A licensee whose licence has been cancelled may appeal to the Central Government within three months of the date of the order.

*Amended by S. O. No. 2139 dated 12-8-1972 (Govt. of India Notification No. X. 11014/12/72-D, dated the 5th June, 1972).

******Added by S. O. No. 903, dated 28-2-1976 (Govt. of India Notification No. 11013/2/75-D&MS, dated the 10th February, 1976).

36. *Import of drugs for personal use.*—Small quantities of drugs, the import of which is otherwise prohibited under Section 10 of the Act, may be imported for personal use subject to the following conditions :—

- (i) the drugs shall form part of a passenger's *bona fide* baggage and shall be the property of, and be intended for, the exclusive personal use of the passenger;
- (ii) the drugs shall be declared to the Customs authorities if they so direct;
- (iii) the quantity of any single drug so imported shall not exceed one hundred average doses :

Provided that the licensing authority may in an exceptional case in any individual case sanction the import of a larger quantity :

*Provided further that any drug, imported for personal use but not forming part of *bona fide* personal baggage, may be allowed to be imported subject to the following conditions, namely :—

- (i) the licensing authority, on an application made to it in Form 12-A is satisfied that the drug is for *bona fide* personal use;
- (ii) the quantity to be imported is reasonable in the opinion of the licensing authority and is covered by prescription from a registered medical practitioner; and
- (iii) the licensing authority grants a permit in respect of the said drug in Form 12-B.

†37. *Packing of patent or proprietary medicines.*—Patent or proprietary medicines shall be imported in containers intended for retail sale.

‡Provided that such medicines may be imported in bulk containers by any person who holds a licence to manufacture, if such person has obtained permission in writing to import such medicines from the licensing authority at least three months prior to the date of import and the imports are made within a period of twelve months from the date of issue of such permission.

38. *Statement to accompany imported drugs.*—All consignments of drugs sought to be imported shall be accompanied by an invoice or other statement showing the name and address of the manufacturer and the names and quantities of the drugs.

39. *Documents to be supplied to the Customs Collector.*—Before drugs for the import of which a licence is not required are imported a declaration signed by or on behalf of the manufacturer or by or on behalf of the importer that the drugs comply with the provisions of Chapter III of the Drugs and Cosmetics Act, 1940 and the Rules thereunder shall be supplied to the Customs Collector.

*Added under Government of India Notification No. F. 1-36/54-D.S., dated 3rd March, 1955.

†Amended by Government of India Notification No. F. 1-3/51-D. S., dated 15th October, 1954.

‡Amended by Government of India Notification No. F. 1-45/58-D, dated 4th January, 1961.

*40. *Procedure for the import of drugs.*—(1) If the Customs Collector has reason to doubt whether any drugs comply with the provisions of Chapter III of the Act and Rules thereunder he may, and if requested by an officer appointed for this purpose by the Central Government shall, take samples of any drugs in the consignment and forward them to the Director of the laboratory appointed for this purpose by the Central Government and may detain the drugs in the consignment of which samples have been taken until the report of the Director of the said laboratory or any other officer empowered by him on this behalf, subject to the approval of the Central Government, on such samples is received :

Provided that if the importer gives an undertaking in writing not to dispose of the drugs without the consent of the Customs Collector and to return the consignment or such portion thereof as may be required, the Customs Collector shall make over the consignment to the importer.

(2) If an importer who has given an undertaking under the proviso to sub-rule (1) is required by the Customs Collector to return the consignment or any portion thereof he shall return the consignment or portion thereof within ten days of receipt of the notice.

†41. (1) If the Director of the laboratory appointed for the purpose by the Central Government or any other officer empowered by him on this behalf, subject to the approval of the Central Government, reports to the Customs Collector that the samples of any drug in a consignment are not of standard quality, or that the drug contravenes in any other respect the provisions of Chapter III of the Act or the Rules thereunder and that the contravention is such that it cannot be remedied by the importer, the Customs Collector shall communicate the report forthwith to the importer who shall, within two months of his receiving the communication either export all the drugs of that description in the consignment, to the country in which they were manufactured or forfeit them to the Central Government which shall cause them to be destroyed :

Provided that the importer may within fifteen days of receipt of the report make a representation against the report to the Customs Collector, and the Customs Collector shall forward the representation with a further sample to the licensing authority, who after obtaining, if necessary, the report of the Director of the Central Drugs Laboratory, shall pass orders thereon which shall be final.

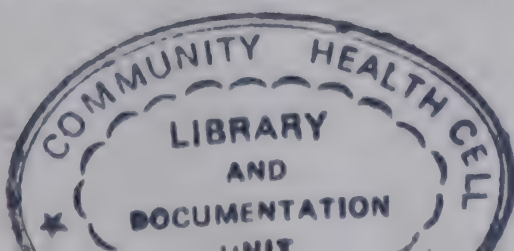
‡(2) If the Director of the laboratory appointed for the purpose by the Central Government or any other officer empowered by him on this behalf, subject to the approval of the Central Government reports to the Customs Collector that the samples of any drug contravene in any respect the provisions of Chapter III of the Act or the Rules thereunder and that the contravention is such that it can be remedied by the importer, the Customs Collector shall communicate the report forthwith to the importer and permit him

*Amended by the Government of India Notification No. F. 1—99/52-D.S., dated 3rd November, 1953.

†Amended by Government of India Notification No. F. 7-7/47-D, dated 5th January, 1954.

‡Added under Government of India Notification No. 7-11/47-D, dated 5th October, 1951.

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to import the drug on his giving an undertaking in writing not to dispose of the drug without the permission of the officer authorised in this behalf by the Central Government.

*42.

43. The drugs specified in Schedule D shall be exempt from the provisions of Chapter III of the Act and of the Rules made thereunder to the extent, and subject to the conditions specified in that Schedule.

**43A. No drug shall be imported into India except through one of the following places, namely :—

Ferozepore Cantonment and Amritsar Railway Stations :

In respect of drugs imported by rail across the frontier with East Pakistan.

Ranaghat, Bongaon and Mohiassan Railway Stations :

In respect of drugs imported by rail across the frontier with East Pakistan.

Castle Rock Railway Station :

In respect of drugs imported by rail across the frontier with Goa.

Madras, Calcutta, Bombay, Cochin and Visakhapatnam :

In respect of drugs imported by sea into India.

Madras, Calcutta, Bombay, Delhi and Ahmedabad :

In respect of drugs imported by air into India.

†43-B. Drugs, consignments of which are in transit through India to foreign countries and which shall not be sold or distributed in India shall be exempted from the requirements of Chapter III of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules made thereunder.

Provided that if the Government of the countries to which the drugs are consigned regulate their import by the grant of import licences, the importer shall at the time of import into India, produce such import licences.

PART V—GOVERNMENT ANALYSTS AND INSPECTORS

‡44. *Qualifications of Government Analyst.*—A person appointed as a Government Analyst under the Act shall be a person who—

(a) is a graduate in medicine or science or pharmacy or pharmaceutical chemistry of a University recognised for this purpose

*Omitted by Government of India Notification No. F. 1-9/52-DS., dated 3rd November, 1953.

**Amended by the Government of India Notification No. F. 7-7/47-D, dated 5th January, 1954.

†Added under Government of India Notification No. E. 1-60/D, dated 19th March, 1964.

‡Amended by G. S. R. No. 1427 dated 22-10-77 (Govt. of India Notification No. X. 11013/2/76-D & MS dated the 10th October, 1977)

- by the appointing authority and has had not less than five years' post-graduate experience in the testing of drugs in a laboratory under control of (i) a Government Analyst appointed under the Act, or (ii) the head of an Institution or testing laboratory approved for the purpose by the appointing authority, or
- (b) possesses a post-graduate degree in medicine or science or pharmacy or pharmaceutical chemistry of a University recognised for the purpose by the appointing authority or possesses the Associateship Diploma of the Institution of Chemists (India) obtained by passing the said examination with 'Analysis of Drugs and Pharmaceuticals' as one of the subjects and has had after obtaining the said post-graduate degree or diploma not less than three years' experience in the testing of drugs in a laboratory under the control of (i) a Government Analyst appointed under the Act, or (ii) the head of an Institution or testing laboratory approved for the purpose by the appointing authority;

Provided that—

- (i) for the purpose of examination of items in Schedule C, the person appointed under clause (a) or clause (b) should be able to produce evidence of satisfactory training in physiology, bacteriology or serology or pathology or pharmacology or microbiology and should have experience of testing of the said items, in an institution or testing laboratory approved by the appointing authority, for a period of not less than five years in the case of a person appointed under clause (a) and of not less than three years in the case of a person appointed under clause (b) :
- (ii) for a period of four years from the date on which Chapter IV of the Act takes effect in the States, persons whose training and experience are regarded by the appointing authority as affording, subject to such further training, if any, as may be considered necessary, a reasonable guarantee of adequate knowledge and competence, may be appointed as Government Analysts. The persons so appointed may, if the appointing authority so desires, continue in service after the expiry of the said period of four years :
- (iii) no person who is engaged directly or indirectly in any trade or business connected with the manufacture of drugs shall be appointed as a Government Analyst for any area :

Provided further that for the purpose of examination of Antisera, Toxoid and Vaccines and Diagnostic Antigens for Veterinary use, the person appointed shall be a person who is a graduate in Veterinary Science, or general science, or medicine or pharmacy and has had not less than five years' experience in the standardisation of biological products or person holding a post-graduate degree in Veterinary Science, or general science, or medicine or pharmacy or pharmaceutical chemistry with an experience of not less than three years in the standardisation of biological products :

Provided also that persons, already appointed as Government Analysts may continue to remain in service, if the appointing

authority so desires, notwithstanding the fact that they do not fulfil the qualifications as laid down in clause (a), clause (b) or the preceding proviso.

45. *Duties of Government Analysts.*—(1) The Government Analyst shall cause to be analysed or tested such samples of drugs ~~**~~and cosmetics as may be sent to him by Inspectors or other persons under the provisions of Chapter IV of the Act and shall furnish reports of the results of test or analysis in accordance with these Rules.

(2) A Government Analyst shall from time to time forward to the Government reports giving the result of analytical work and research with a view to their publication at the discretion of Government.

46. *Procedure on receipt of sample.*—On receipt of a package from an Inspector containing a sample for test or analysis, the Government Analyst shall compare the seals on the packet with the specimen impression received separately and shall note the condition of the seals on the package. After the test or analysis has been completed, he shall forthwith supply to the Inspector a report in triplicate in Form 13 of the result of the test or analysis, together with full protocols of the tests or analysis applied :

**Explanation.*—It shall be deemed to be full and sufficient compliance with the requirement of the rule in respect of the supply of "protocols" of the tests or analysis applied", if—

- (1) for pharmacopoeial drug, where the tests or methods of analysis prescribed in the official pharmacopoeia are followed, references to the specific tests or analysis in the pharmacopoeias are given in the report;
- (2) for patent or proprietary medicines for which the tests and methods prescribed in any of the official pharmacopoeias are applicable and are followed, references to the specific tests or analysis in the pharmacopoeias are given in the report;
- (3) for patent or proprietary medicines containing pharmacopoeial drugs for which the official tests or analysis or methods of assays are modified and applied, a description of the actual tests or, as the case may be, analysis or methods of assays so applied is given in the report;
- (4) for patent or proprietary medicines for which no pharmacopoeial tests or methods of analysis are available or can be applied but for which tests or methods of analysis given in standard books or journals are followed, a description of such tests or methods of analysis applied together with the reference to the relevant books or journals from which the tests or methods of analysis have been adopted, is given in the report;
- (5) for those drugs for which methods of test are not available and have been evolved by the Government Analyst, a description of tests applied is given in the report.

**Added by S. O. No. 2139 dated 12-8-1972 (Govt. of India Notification No. K. 11014/12/72-D dated the 5th June, 1972).

†Added under Government of India Notification No. F. 1-60/61-D, dated 12th July, 1962.

47. *Report of result of test or analysis.*—An application from a purchaser for test or analysis of a drug under Section 26 of the Act shall be made in Form 14 A and the report of test or analysis of the drug made on such application shall be supplied to the applicant in Form 14-B.

48. *Fees.*—The fees to be paid by a person submitting to the Government Analyst under Section 26 of the Act for test or analysis of a drug purchased by him shall be those specified in Schedule B.

49. *Qualification of Inspectors.*—A person who is appointed an Inspector under the Act shall be a person who—

*(a) has a degree in Pharmacy or Pharmaceutical Chemistry or a post-graduate degree in Chemistry with pharmaceutics as a special subject of a University recognised for this purpose by the appointing authority or the Associateship Diploma of the Institution of Chemists (India) obtained by passing the examination with "Analysis of Drugs and Pharmaceuticals" as one of the subjects; or

(aa) holds the Pharmaceutical Chemists diploma granted by the Pharmaceutical Society of Great Britain; or

†(b)

(c) is a graduate in medicine or science of a University recognized for this purpose by the appointing authority and has had at least one year's post-graduate training in a laboratory under (i) a Government Analyst appointed under the Act, or (ii) a Chemical Examiner, or (iii) a Fellow of the Royal Institute of Chemistry of Great Britain (Branch E), or (iv) the head of an institution specially approved for the purpose by the appointing authority;

Provided that only those Inspectors who have had not less than three years' experience in the manufacture or testing of substances specified in Schedule C in a laboratory approved for this purpose by the licensing authority, shall be authorized to inspect the manufacture of items mentioned in Schedule C :

Provided further that for a period of four years from the date on which Chapter IV of the Act takes effect in the States, persons whose qualifications, training and experience are regarded by the appointing authority as affording, subject to such further training, if any, as may be considered necessary, a reasonable guarantee of adequate knowledge and competence may be appointed as Inspectors and authorized under the preceding proviso :

**Provided further that any person appointed as Inspector in terms of the preceding proviso may be allowed to hold his post after the said period of four years, if the State Government is satisfied that he possesses adequate knowledge and competence as Inspector to inspect the manufacture of items mentioned in Schedule C.

*Amended under Government of India Notification No. F. 1-60/61-D, dated 17th July, 1962.

†Omitted under Government of India Notification No. F. 1-45/58-D, dated 4th January, 1961.

**Added by S. O. No. 2139 dated 12-8-1972 (Govt. of India Notification [No. X.11014/12/72-D, dated 5th June, 1972]).

*Provided further for the purposes of inspection of shops in any specified area any officer of the medical or public health department who is a registered medical practitioner or a graduate in science may be appointed an ex-officio Inspector.

**Provided further that only Inspectors who are graduates in veterinary science or medicine or general science or pharmacy and have had not less than three years' experience in the manufacture or testing of biological products shall be authorised to inspect the manufacture of veterinary biological products.

†50. *Controlling authority.*—(1) All Inspectors appointed by the Central Government shall be under the control of an officer appointed in this behalf by the Central Government.

(2) All Inspectors appointed by the State Government shall be under the control of an officer appointed in this behalf by the State Government.

(3) For the purposes of these rules an officer appointed by the Central Government under sub-rule (1), or as the case may be, an officer appointed by the State Government under sub-rule (2), shall be a controlling authority.

51. *Duties of Inspectors of premises licensed for sale.*—Subject to the instructions of the controlling authority, it shall be the duty of an Inspector authorized to inspect premises licensed for the sale of drugs—

- (1) to inspect not less than twice a year all establishments licensed for the sale of drugs within the area assigned to him;
- (2) to satisfy himself that the conditions of the licences are being observed;
- (3) to procure and send for test or analysis, if necessary, imported packages which he has reason to suspect contain drugs being sold or stocked or exhibited for sale in contravention of the provisions of the Act or Rules thereunder;
- (4) to investigate any complaint in writing which may be made to him;
- (5) to institute prosecutions in respect of breaches of the Act and Rules thereunder;
- (6) to maintain a record of all inspections made and action taken by him in the performance of his duties, including the taking of samples and the seizure of stocks, and to submit copies of such record to the controlling authority;
- (7) to make such enquiries and inspections as may be necessary to detect the sale of drugs in contravention of the Act;

*Amended by Government of India Notification No. DR/49F. 1-26/54-DS, dated 19th February, 1955.

**Added under Govt. of India, Ministry of Health, F. P. W. H. and U. D. Notification No. F. 1-6/62-D, dated the 2nd July, 1969.

† Ammended by S.O. No.2139 dated 12-8-1972 (Govt. of India Notification No. X. 11014/12/72-D, dated the 5th June, 1972).

- (8) when so authorized by the State Government, to detain imported packages which he has reason to suspect contain drugs, the import of which is prohibited.

52. *Duties of Inspectors specially authorised to inspect the manufacture of drugs.*—Subject to the instructions of the controlling authority it shall be the duty of an Inspector authorized to inspect the manufacture of drugs—

- (1) to inspect not less than twice a year, all premises licensed for manufacture of drugs within the area allotted to him and to satisfy himself that the conditions of the licence and provisions of the Act and Rules thereunder are being observed;
- (2) in the case of establishments licensed to manufacture products specified in Schedules C and C(1) to inspect the plant and the process of manufacture, the means employed for standardizing and testing the drug, the methods and place of storage, the technical qualifications of the staff employed and all details of location, construction and administration of the establishment likely to affect the potency or purity of the product;
- (3) to send forthwith to the controlling authority after each inspection a detailed report indicating the conditions of the licence and provisions of the Act and Rules thereunder which are being observed and the conditions and provisions, if any, which are not being observed.
- (4) to take samples of the drugs manufactured on the premises and sent them for test or analysis in accordance with these Rules;
- (5) to institute prosecutions in respect of breaches of the Act and Rules thereunder.

53. *Prohibition of disclosure of information.*—Except for the purposes of official business or when required by a Court of Law, an Inspector shall not, without the sanction in writing of his official superior, disclose to any person any information acquired by him in the course of his official duties

54. *Form of order not to dispose of stock.*—An order in writing by an Inspector under clause (c) of Section 22 of the Act requiring a person not to dispose of any stock in his possession shall be in Form 15.

*54-A. *Prohibition of sale.*—No person in possession of a drug in respect of which an Inspector has made an order under clause (c) of sub-section (i) of Section 22 of the Act shall in contravention of that order sell or otherwise dispose of any stock of such drug.

*55. *Form of receipts for seized drug, cosmetic, record register, document or any other material object :—*

A receipt by an Inspector for the stock of any drug or cosmetic or for any record, register, document or any other material object seized by him under clause (c) or clause (cc) of sub-section (1) of Section 22 of the Act shall be in Form 16.

*Added under Government of India Notification No. F. 1-19/59-D, dated 13th June, 1961.

**Amended by GSR No. 926 dated 16-7-1977 (Govt. of India Notification No. X. 11014/6/76-D & MS dated 24-6-1977).

56. *Form of intimation of purpose of taking samples.*—When an Inspector takes a sample of a drug for the purpose of test or analysis, he shall intimate such purpose in writing in Form 17 to the person from whom he takes it.

57. *Procedure for despatch of sample to Government Analyst.*—(1) The portion of sample or the container sent by an Inspector to the Government Analyst for test or analysis under sub-section (4) of Section 23 of the Act shall be sent by registered post or by hand in a sealed packet, enclosed together with a memorandum in Form 18, in an outer cover addressed to the Government Analyst.

(2) A copy of the memorandum and a specimen impression of the seal used to seal the packet shall be sent to the Government Analyst separately by registered post or by hand.

*58. *Confiscation of drugs, implements, machinery etc.*—

(1) Where any person has been convicted for contravening any of the provisions of Chapter IV of the Act or any rule made thereunder, the stock of the drug in respect of which the contravention has been made shall be liable to confiscation.

(2) Where any person has been convicted for the manufacture of any drug deemed to be misbranded under clause (a), clause (b), clause (c), clause (d), clause (f) or clause (g) of section 17 of the Act, or adulterated drug under section 17B of the Act, or for manufacture for sale, or stocking or exhibiting for sale or distribution of any drug without a valid licence as required under clause (c) of section 18 of the Act, any implements or machinery used in such manufacture, sale or distribution and any receptacle, packages, or coverings in which such drug is contained and the animals, vehicles, vessels or other conveyances used in carrying such drug shall also be liable to confiscation.

**58-A. *Procedure for disposal of confiscated drugs.*—(1) The Court shall refer the confiscated drugs to the Inspector concerned for report as to whether they are of standard quality or contravene the provisions of the Act or the Rules in any respect.

(2) If the Inspector, on the basis of Government Analyst's report finds the confiscated drugs to be not of standard quality or to contravene any of the provisions of the Act or the Rules made thereunder, he shall report to the Court accordingly. The Court shall thereupon order the destruction of the drugs. The destruction shall take place under the supervision of the Inspector in the presence of such authority, if any, as may be specified by the Court.

(3) If the Inspector finds that the confiscated drugs are of standard quality and do not contravene the provisions of the Act or the Rules made

*Amended by S. O. No. 289, dated 3-2-1973 (Govt. of India Notification No. X. 11014/17/72-D, dated the 20th December, 1972).

**Added under Government of India Notification No. F. 1-9 62-D, dated 2nd Dec. 1964.

thereunder, he shall report to the Court accordingly. The Court may then order the sale of the drugs by public auction to any party holding a requisite licence under the Act.

PART VI—SALE OF DRUGS OTHER THAN HOMOEOPATHIC MEDICINES

59. (1) The State Government shall appoint Licensing Authorities for the purpose of this Part for such areas as may be specified.

(2) Applications for the grant or renewal of a licence to sell, stock or exhibit for sale, or distribute drugs shall be made in Form 19 or Form 19-A, as the case may be, to the licensing authority and shall be accompanied by a fee of rupees twenty :

Provided that in the case of an itinerant vendor or an applicant who desires to establish a shop in a village or town having a population of 5,000 or less the application in Form 19-A shall be accompanied by a fee of rupees five.

(3) A fee of rupees five and in the case of an itinerant vendor or an applicant who desires to establish a shop in a village or town having a population of 5,000 or less, a fee of rupee one and twentyfive paise shall be paid for a duplicate copy of a licence issued under this rule, if the original is defaced, damaged or lost :

*Provided that if the applicant applies for the renewal of a licence after its expiry but within six months of such expiry the fee payable for renewal of such licence shall be rupees twenty plus an additional fee at the rate of rupees twenty per month or part thereof, and in the case of itinerant vendor or an applicant desiring to open a shop in village or town having a population of 5,000 or less the fee shall be rupees five plus an additional fee at the rate of rupees five per month or part thereof.

**60. A licensing authority may with the approval of the State Government by an order in writing delegate the power to sign licences and such other powers as may be specified in the order to any other person under his control.

61. *Forms of licences to sell drugs.*—(1) A licence to sell, stock or exhibit for sale, or distribute drugs other than those specified in Schedules C and C(1) by retail, on restricted licence or by wholesale shall be issued in Form 20, 20-A or 20-B as the case may be :

Provided that a licence in Form 20-A shall be valid for only such drugs as are specified in the licence;

**(2) A licence to sell, stock or exhibit for sale, or distribute drugs specified in Schedule C and C(1) by retail, on restricted licence or by wholesale shall be issued in Form 21, 21-A or 21-B, as the case may be :

Provided that a licence in Form 21-A shall be valid for only such drugs as are specified in the licence.

*Amended by S. O. No. 2139 dated 12-8-1972 (Govt. of India Notification No. X. 11014/12/72, —D, dated the 5th June, 1972).

**Amended by Government of India Notification No. F. 1-16/57-D, dated 15th June, 1957.

62. *Sale at more than one place.*—If drugs are sold or stocked for sale at more than one place, separate application shall be made, and a separate licence shall be issued, in respect of each such place :

†Provided that this shall not apply to itinerant vendors who have no specified place of business and who will be licensed to conduct business in a particular area within the jurisdiction of the licensing authority.

†62A. *Restricted licences in Forms 20-A and 21-A.*—(a) Restricted licences in Forms 20-A and 21-A shall be issued, subject to the discretion of the Licensing Authority, to dealers or persons in respect of drugs whose sale does not require the supervision of a qualified person.

(b) Licences to itinerant vendors shall be issued only in exceptional circumstances for *bona fide* travelling agents of firms dealing in drugs or for a vendor who purchases drugs from a licensed dealer for distribution in sparsely populated rural areas where other channels of distribution of drugs are not available.

(c) The licensing authority may issue a licence in Form 21-A to a travelling agent of a firm but to no other class of itinerant vendors for the specific purpose of distribution to medical practitioners or dealers, samples of biological and other special products specified in Schedule C :

Provided that travelling agents of licensed manufacturers, agents of such manufacturers and importers of drugs shall be exempted from taking out licence for the free distribution of samples of medicines among members of the medical profession, hospitals, dispensaries and the medical institution or research institutions.

*62-B. *Conditions to be satisfied before a licence in Form 20-A or Form 21-A is granted.*—(1) A licence in Form 20-A or Form 21-A shall not be granted to any person, unless the authority empowered to grant the licence is satisfied that the premises in respect of which the licence is to be granted are adequate and equipped with proper storage accommodation for preserving the properties of drugs to which the licence applies :

Provided that this condition shall not apply in the case of licence granted itinerant vendors.

(2) In granting a licence under Rule 62-A the authority empowered to grant it shall have regard to :—

- (i) the number of licences granted in the locality during one year immediately preceding; and
- (ii) the occupation, trade or business carried on by such applicant :

Provided that the licensing authority may refuse to grant or renew a licence to any applicant or licensee in respect of whom it is satisfied that by reason of his conviction of an offence under the Act or these Rules or the previous cancellation or suspension of any licence granted thereunder, he is not a fit person to whom a licence should be granted under this Rule.

†Added under Government of India Notification No. F. 10-21/49-D, dated 10th March, 1953.

*Added under Government of India Notification No. F. 1-9/60-D, dated 3rd July, 1961.

(3) Any person who is aggrieved by the order passed by the licensing authority in sub-rule (1) may, within 30 days from the date of the receipt of such order appeal to the State Government and the State Government may, after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for representing his views in the matter make such order in relation thereto as it thinks fit.

(a 62C'. Application for licence to sell drugs by wholesale or to distribute the same from a motor vehicle :—

(a) Application for the grant or renewal of a licence to sell by wholesale or to distribute from a motor vehicle shall be made to the Licensing Authority in Form 19-AA and shall be accompanied by a fee of rupees twenty :

Provided that if the applicant applies for the renewal of a licence after its expiry but within six months of such expiry, the fee payable for renewal of such licence shall be rupees twenty plus an additional fee at the rate of rupees twenty per month or part thereof.

(2) A fee of rupees five shall be paid for a duplicate copy of a licence issued under this rule, if the original is defaced, damaged or lost.

@62D.—Form of licences to sell drugs by wholesale or distribute drugs from a motor vehicles :—

A licence shall be issued for sale by wholesale or for distribution from a motor vehicle of drugs other than those specified in Schedule and Schedule C(1) in Form 20BB and of drugs specified in Schedule C and Schedule C(1) in Form 21BB :

Provided that such a licence shall not be required in a case where a public carrier or a hired vehicle is used for transportation or distribution of drug.

**63. Duration of licence.—*An original licence or a renewed licence to sell drugs, unless sooner suspended or cancelled, shall be valid up to the 31st December of the year following the year in which it is granted or renewed :

****Provided that if the application for renewal of licence in force is made before its expiry or if the application is made within six months of its expiry, after payment of additional fee, the licence shall continue to be in force until orders are passed on the application. The licence shall be deemed to have expired if application for its renewal is not made within six months after its expiry.

*†63A. Certificate of renewal of a sale licence.—*The certificate of renewal of a sale licence in Forms 20, 20-A, 20-B, 21, 21-A, and 21-B shall be issued in Form 21-C.

*Amended by Government of India Notification No. F. 1-10/62-D, dated 10th April, 1964.

**Amended by S. O. No. 2139, dated 12th August, 1972 (Govt. of India Notification No. X. 11014/12/72)D, dated the 5th June, 1972).

†Added under Government of India Notification No. F. 1-10/62-D, dated 10th April, 1964.

@63B. *Certificate of renewal of licence.*—A certificate of renewal of a licence in Form 20BB or Form 21BB shall be issued in Form 21-CC.;

‡64. *Conditions to be satisfied before a licence in Form 20, 20-B 21 or 21-B is granted.*—(1) A licence in Form 20, 20-B, 21 or 21-B to sell, stock or exhibit for sale, or distribute drugs shall not be granted to any person unless the authority empowered to grant the licence is satisfied that the premises in respect of which the licence is to be granted are adequate, equipped with proper storage accommodation for preserving the properties of the drugs to which the licence applies and are in charge of a person competent in the opinion of the licensing authority to supervise and control the sale, distribution and preservation of drugs :

Provided that in the case of a pharmacy a licence in Form 20 or 21 shall not be granted unless the licensing authority is satisfied that the requirements prescribed for a pharmacy in Schedule N have been complied with.

Explanation.—For the purpose of this rule the term 'Pharmacy' shall be held to mean to include every store or shop or other place : (1) where drugs are dispensed, that is, measured or weighed or made up and supplied; or (2), where prescriptions are compounded; or (3) where drugs are prepared; or (4) which has upon it or displayed within it, or affixed to or used in connection with it, a sign bearing the word or words "Pharmacy", "Pharmacist," "Dispensing Chemist" or "Pharmaceutical Chemist"; or (5) which, by sign, symbol or indication within or upon it gives the impression that the operations mentioned at (1), (2) and (3) are carried out in the premises; or (6) which is advertised in terms referred to in (4) above.

(2) In granting a licence under sub-rule (1) the authority empowered to grant it shall have regard—

*(i) to the average number of licences granted during the period of 3 years immediately preceding, and

(ii) to the occupation, trade or business ordinarily carried on by such applicant during the period aforesaid :

Provided that the licensing authority may refuse to grant or renew a licence to any applicant or licensee in respect of whom it is satisfied that by reason of his conviction of an offence under the Act or these Rules, or the previous cancellation or suspension of any licence granted thereunder, he is not a fit person to whom a licence should be granted under this rule. Every such order shall be communicated to the licensee as soon as possible.

†(3) Any person who is aggrieved by the order passed by the licensing authority in sub-rule(1) may, within 30 days from the date of the receipt of such order, appeal to the State Government and the State Government may, after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for representing his views in the matter, make such order in relation thereto as it thinks fit.

@Added by Govt. of India Notification No. X11C13/7/76—DGHS dated the 25th January 1979.

*Amended by Government of India Notification No. F. 1-19/59-D, dated 13th June, 1961.

†Amended by Government of India Notification No. F. 1-2/60-D, dated 3rd July, 1961.

‡Amended by Government of India Notification No. F. 1-16/57-D, dated 15th Jun. 1957 and No. F. 1-19/59-D, dated 13th June, 1961.

65. *Condition of licences.*—Licences in Form 20, 20-A, 20-B, 21, 21-A and 21-B shall be subject to the conditions stated therein and to the following general conditions—

(1) Any drug specified in Schedule E or any preparation containing any such drug and any drug supplied on a prescription shall, if compounded or made up on the licensee's premises, be compounded or made up by or under the direct and personal supervision of a qualified person.

(2) The supply, otherwise than by way of wholesale dealing, of a drug specified in Schedule E or any preparation containing any such drug, and of any drug supplied on the prescription of a Registered Medical Practitioner shall be effected only by or under the personal supervision of a qualified person.

‡(3) (1) The supply of any drug on a prescription of a Registered Medical Practitioner shall be recorded at the time of supply in a prescription register specially maintained for the purpose and the serial number of the entry in the register shall be entered on the prescription. The following particulars shall be entered in the register :—

- (a) serial number of the entry,
- (b) the date of supply,
- (c) the name and address of the prescriber,

** (d) the name and address of the patient, or the name and address of the owner of the animal if the drug supplied is for veterinary use.

(e) the name of the drug or preparation and the quantity or in the case of a medicine made up by the licensee, the ingredients and quantities thereof,

(f) in the case of a drug specified in Schedule C, Schedule H or Schedule L, the name of the manufacturer of the drug, its batch number and the date of expiry of potency, if any,

(g) the signature of the qualified person by or under whose supervision the medicine was made up or supplied.

Provided that in the case of drugs which are not compounded in the premises and which are supplied from or in the original containers, the particulars specified in items (a) to (g) above may be entered in a cash or credit memo book, serially numbered and specially maintained for this purpose :

Provided further that if the medicine is supplied on a prescription on which the medicine has been supplied on a previous occasion and entries made in the prescription register, it shall be sufficient if the new entry in the register includes a serial number, the date of supply, the quantity supplied and a sufficient reference to an entry in the register recording the dispensing of the medicine on the previous occasion.

‡Amended by S. O. No. 2139, dated 12-8-1972 (Govt. of India Notification No. X. 11014/12/72-D, dated the 5th June, 1972.)

**Amended by GSR No. 926 dated 16-7-1977, (Govt. of India Notification No. X. 11014/6/76-D & M.S. dated 24-6-77).

Provided further that it shall not be necessary to record the above details in the register or in the cash or credit memo particulars in respect of :—

- (i) any drugs supplied against prescription under the Employees State Insurance Scheme if all the above particulars are given in that prescription, and
- (ii) any drug other than that specified in Schedule C, E or L if it is supplied in the original unopened container of the manufacturer and if the prescription is duly stamped at the time of supply with the name of the supplier and the date on which the supply was made and on condition that the provisions of sub-rule (4)(3) of this rule are complied with.

(2) The option to maintain a prescription register or a cash or credit memo book in respect of drugs and medicines which are supplied from or in the original container, shall be made in writing to the Licensing Authority at the time of application for the grant or renewal of the licence to sell by retail.

Provided that the Licensing Authority may require records to be maintained only in prescription register if it is satisfied that the entries in the carbon copy of the cash or credit memo book are not legible.

*(4) (1) The supply by retail, otherwise than on a prescription of a drug specified in Schedule C or Schedule E shall be recorded at the time of supply either :

- (i) in a register specially maintained for the purpose in which the following particulars shall be entered :—
 - (a) serial number of the entry,
 - (b) the date of supply,
 - (c) the name and address of the purchaser,
 - (d) the name of the drug and the quantity thereof,
 - (e) in the case of a drug specified in Schedule C, the name of the manufacturer, the batch number and the date of expiry of potency,
 - (f) the signature of the person under whose supervision the sale was effected, or
- (ii) in a cash or credit memo book, serially numbered containing all the particulars specified in items (b) to (f) of sub-clause (i) above.

NOTE :—The entries in the carbon copy of the cash or credit memo which is retained by the licensee shall be maintained in a legible manner.

(2) The option to maintain a register or a cash or credit memo book shall be made in writing to the Licensing Authority at the time of application for the grant or renewal of a licence to sell by retail :

Provided that the Licensing Authority may require records to be maintained in a register if it is satisfied that the entries in the carbon copy of the cash/credit memo book are not legible.

(3) ^{*}(i) The supply by retail of any drug shall be made against a cash/credit memo which shall contain the following particulars :—

(a) Name, address and sale licence number of the dealer,

^{**}(b) Serial number of the cash/credit memo,

(c) the name and quantity of the drug supplied.

(ii) Carbon copies of cash/credit memos shall be maintained by the licensee as record.

(4) Records of purchase of a drug intended for sale or sold by retail shall be maintained by the licensee and such records shall include the following particulars.

(a) the date of purchase,

(b) the name, address of the person from whom purchased and the number of the relevant licence held by him,

(c) the name of the drug, the quantity and the batch number,

(d) the name of the manufacturer of the drug.

^{*}(5) (1) Subject to the other provisions of these rules the supply of a drug by wholesale shall be made against a cash or credit memo bearing the name and address of the licensee and his licence number under the Drugs and Cosmetics Act in which the following particulars shall be entered—

(a) the date of sale.

(b) the name, address of the licensee to whom sold and his sale licence number. In case of sale to an authority purchasing on behalf of Government, or to a hospital, medical, educational or research institution or to a Registered Medical Practitioner for the purpose of supply to his patients the name and address of the authority, institution or the Registered Medical Practitioner as the case may be,

(c) the name of the drug, the quantity and the batch number,

(d) the name of the manufacturer.

(2) Carbon copies of cash or credit memos specified in clause (1) shall be preserved as records for a period of three years from the date of the sale of the drug.

(3) Records of purchase of a drug intended for resale or sold by wholesale shall be maintained by the licensee and such records shall include the following particulars—

(a) the date of purchase,

(b) the name, address and the number of the relevant licence held by the person from whom purchased,

(c) the name of the drug, the quantity and the batch number,

(d) the name of the manufacturer of the drug.

^{**}Added by G. S. R. No. 245 dated 21-2-1976 (Govt. of India Notification No X. 11013/5/72-D&M.S. dated the 3rd, February, 1976).

^{*}Amended by Government of India Notification No. F. 1-63/62-D, dated 17th July, 1963.

(6) The licensee shall produce for inspection by an Inspector appointed under the Act on demand all registers and records maintained under these Rules, and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and Rules thereunder have been observed.

(7) Except where otherwise provided in these Rules, all registers and records maintained under these Rules shall be preserved for a period of not less than two years from the date of the last entry therein.

(8) Notwithstanding anything contained in this Rule it shall not be necessary to record particulars in a register specially maintained for the purpose if the particulars are recorded in any other register specially maintained under any other law for the time being in force.

*(9) Substances specified in Schedules H and L and preparations containing such substances shall not be sold by retail except on and in accordance with a prescription of a Registered Medical Practitioner.

Provided that no prescription shall be required for sale or supply to a Registered Medical Practitioner, hospital, infirmary or an institutional approved by an order of a Licensing Authority.

(10) For the purposes of clause (9) a prescription shall—

- (a) be in writing and be signed by the person giving it with his usual signature and be dated by him;
- *** (b) specify the name and address of the person for whose treatment it is given, or the name and address of the owner of the animal if the drug is meant for veterinary use;
- (c) indicate the total amount of the medicine to be supplied and the dose to be taken.

(11) The person dispensing a prescription containing a drug specified in Schedule H shall comply with the following requirements in addition to other requirements of these Rules—

- (a) the prescription must not be dispensed more than once unless the prescriber has stated thereon that it may be dispensed more than once;
- (b) if the prescription contains a direction that it may be dispensed a stated number of times or at stated intervals it must not be dispensed otherwise than in accordance with the directions;
- (c) at the time of dispensing there must be noted on the prescription above the signature of the prescriber the name and address of the seller and the date on which the prescription is dispensed.

** (11-A) No person dispensing a prescription containing substances specified in Schedule H or L, may supply any other preparation, whether containing the same substance or not, in lieu thereof.

*Amended by Government of India. Notification No. F. 1-31/47-D, dated 13th March, 1950, and No. F. 1-88/57-D, dated 28th February, 1958.

***Amended by G. S. R. No. 926, dated 16-7-1977 (Govt. of India Notification No. X. 11014/6/76—D. & M. S. dated 24/6/1977).

**(12) Substances specified in Schedule E other than in a form ready for internal or external use and kept in a retail shop or premises used in connection therewith shall be stored—

- (a) in a cupboard or drawer reserved solely for the storage of poisons; or
- (b) in a part of the premises separated from the remainder of the premises and to which customers are not permitted to have access.

(13) Substances specified in Schedule E shall be kept in containers impervious to the poison and sufficiently stout to prevent leakage arising from the ordinary risk of handling and transport.

(14) A substance specified in Schedule E sold by retail shall be labelled with the word "Poison" in such language or languages as the State Government may prescribe by notification in the official Gazette.

*(15) (a) The description "Drugstore" shall be displayed by such licensees who do not require the services of a qualified person.

(b) The description "Chemists and Druggists" shall be displayed by such licensees who employ the services of a "Qualified person" but who do not maintain a "Pharmacy" for compounding against prescriptions:

(c) The description "Pharmacy", "Pharmacist", "Dispensing Chemist" or "Pharmaceutical Chemist" shall be displayed by such licensees who employ the services of a "Qualified person" and maintain a "Pharmacy" for compounding against prescriptions :

†*Explanation* :—For the purpose of this rule :—

(i) A substance specified in Schedule E means a substance specified in column 1 of Schedule E and its preparation excluding preparations exempted under columns 2 or 3 thereof;

(ii) 'Qualified person' means a person who

(a) holds a diploma or degree in pharmacy or pharmaceutical chemistry of an institute approved by the Licensing Authority, or

‡(b) is a registered pharmacist as defined in the Pharmacy Act, 1948.

Provided that in those States (including Union territories) where the first register of Pharmacists under section 29 of the said Act has not been prepared, a person possessing qualifications to have his name entered in that register shall be deemed to be a qualified person till such time as that register is prepared.

**Added by S. O. No. 2139 dated 12-8-1972 (Govt. of India Notification No. X. 11014/12/72-D dated the 5th June, 1972).

*Amended by the Government of India Notification No. F. 1-16/57-D, dated 15th June, 1957.

†Amended by Government of India Notification No. 1-63/61-D dated 17-7-1963.

‡Amended by Government of India, Ministry of Health, F. P., W. H. and U. D. Notification No. F. 1-55/68-D, dated the 17th July, 1969.

††(c) has not less than four years' practical experience of dispensing which is in the opinion of the Licensing Authority adequate and has been approved by that authority as a "qualified person" on or before the 31st December, 1969.

(iii) Date of Expiry of potency means the date that is recorded on the container, label or wrapper as the date up to which the substance may be expected to retain potency not less than or not to acquire toxicity greater than that required or permitted by the prescribed test.

*(16) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.

†(17) No drug shall be sold or stocked by the licensee after the date of expiration of potency recorded on its container, label or wrapper, or in violation of any statement or direction recorded on such container, label or wrapper;

Provided that any such drugs in respect of which the licensee has taken steps with the manufacturer or his representative for the withdrawal, reimbursement or disposal of the same, may be stocked after the date of expiration of potency pending such withdrawal, reimbursement or disposal, as the case may be, subject to the condition that the same shall be stored separately from the trade stocks @and all such drugs shall be kept in packages or cartons, the top of which shall display prominently, the words "Not for sale".

‡(18) No drug intended for distribution to the medical profession as free sample which bears a label on the container as specified in clause (viii) of sub-rule (1) of rule 96, and no drug meant for consumption by the Employees' State Insurance Corporation, the Central Government Health Scheme, the Government Medical Stores Depots, the Armed Forces Medical Stores or other Government institutions, which bears a distinguishing mark or any inscription on the drug or on the label affixed to the container thereof indicating this purpose shall be sold or stocked by the licensee on his premises.

Provided that this sub-rule shall not be applicable to licensees who have been appointed as approved chemists, by the State Government in writing under the Employees State Insurance Scheme for drugs meant for consumption under that Scheme.

*** (19) The supply by retail of any drug in a container other than the one in which the manufacturer has marketed the drug, shall be made only

††Amended by Government of India, Ministry of Health, F. P. W. H. and U. D. Notification No. F. 1-25/69-D, dated 9-12-1969.

‡Added under Government of India, Ministry of Health, F. P., W. H. and U. D. Notification No. 1-113/69-D, dated 23-12-69.

*Amended by Government of India Notification No. F. 1-14/68-D dated 26-10-1968.

†Added under Government of India Notification No. F. 1-55/61-D, dated 22nd August, 1964.

***Added by G. S. R. No. 444 dated 28-4-1973 [Govt. of India Notification No. X. 11014/4/72-D (Pt.) dated the 31st March, 1973].

@Added by S. O. No. 903, dated 28-2-1976 (Govt. of India Notification No. X. 11013/2/75-D & MS. dated 10-2-1976).

by dealers who employ the services of a "qualified person" and such supply shall be made under the direct supervision of the "qualified person" in an envelope or other suitable wrapper or container showing the following particulars on the label:

- (a) name of the drug,
- (b) the quantity supplied,
- (c) the name and address of the dealer.

@@ (20) The medicines for treatment of animals kept in a retail shop or premises shall be labelled with the words 'Not for human use—for treatment of animals only' and shall be stored—

- (a) in a cupboard or drawer reserved solely for the storage of veterinary drugs, or
- (b) in a part of the premises separated from the remainder of the premises to which customers are not permitted to have access.

****65-A.** *Additional information to be furnished by an applicant for licence or a licensee to the Licensing Authority :—*

The applicant for the grant of a licence or any person granted a licence under this Part shall, on demand, furnish to the licensing authority, before the grant of the licence or during the period the licence is in force, as the case may be, documentary evidence in respect of the ownership of occupation or rental or other basis of the premises, specified in the application for licence or in the licence granted, constitution of the firm, or any other relevant matter which may be required for the purpose of verifying the correctness of the statements made by the applicant or the licensee, while applying for or after obtaining the licence, as the case may be.

66. Cancellation and suspension of licences.—(1) The Licensing Authority may, after giving the licensee an opportunity to show cause why such an order should not be passed by an order in writing stating the reasons therefor, cancel a licence issued under this Part or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates, if in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or Rules thereunder :

****Provided that,** where such failure or contravention is the consequence of an act or omission on the part of an agent or employee, the licence shall not be cancelled or suspended if the licensee proves to the satisfaction of the licensing authority :—

- (a) that the act or omission was not instigated or connived at by him or, if the licensee is a firm or company by a partner of the firm or a director of the company, or
- (b) that he or his agent or employee had not been guilty of any similar act or omission within twelve months before the date on which the act or omission in question took place, or where his agent or employee had been guilty of any such act or

@@ Added by G. S. R. No. 926 dated 16-7-1977 (Govt. of India Notification No. X. 11014/6/76-D & MS. dated 24-6-1977).

**Added by S. O. No. 2139, dated 12-8-1972 (Govt. of India Notification No. X.11014/12/72-D, dated the 5th June, 1972)

omission the licensee had not or could not reasonably have had, knowledge of that previous act or omission, or

- (c) if the act or omission was a continuing act or omission, he had not or could not reasonably have had knowledge of that previous act or omission, or
- (d) that he had used due diligence to ensure that the conditions of the licence or the provisions of the Act or the Rules thereunder were observed.

@@ (2) A licensee whose licence has been suspended or cancelled may, within three months of the date of order under sub-rule (1), prefer an appeal against that order to the State Government, which shall decide the same.

PART VI-A—SALE OF HOMOEOPATHIC MEDICINES

*67-A. (1) The State Government shall appoint Licensing Authorities for the purpose of this Part for such areas as may be specified.

(2) Application for the grant or renewal of a licence to sell, stock or exhibit for sale or distribute Homoeopathic medicines shall be made in Form 19-B to the Licensing Authority and shall be accompanied by a fee of rupees five;

**Provided that if the applicant applies for renewal of licence after its expiry but within six months of such expiry the fee payable for renewal of such licence shall be rupees five plus an additional fee at the rate of rupees five per month or part thereof.

@ (3) If the original licence is either defaced, damaged or lost, a duplicate copy thereof may be issued on payment of a fee of rupee one and twenty five paise.

67-B. A Licensing Authority may, with the approval of the State Government, by an order in writing, delegate the power to sign licences and such other powers, as may be specified, to any other person under his control.

67-C. *Forms of licences to sell drugs.*—(1) A licence to sell, stock or exhibit for sale or distribute Homoeopathic medicines by retail or by wholesale shall be issued in Form 20-C or 20-D as the case may be.

67-D. *Sale at more than one place.*—If drugs are sold or stocked for sale at more than one place, a separate application shall be made and a separate licence shall be obtained in respect of each place.

67-E. *Duration of licences.*—An original licence or a renewed licence unless it is sooner suspended or cancelled shall be valid upto the 31st December of the year following the year in which it is granted or renewed :

**Provided that if the application for renewal of a licence in force is made before its expiry or if the application is made within six month of

*Added under Government of India Notification No. F. 1-35/64-D, dated 18th August, 1964.

@ Added by G. S. R. No. 665, dated 28-5-77 (Govt. of India Notification No. X. 11014/2/77-D & M. S., dated 6-5-1977).

@@ Amended by G. S. R. No. 926 dated 16-7-1977 (Govt. of India Notification No. X. 11014/6/76-D & M. S. dated 24-6-1977).

**Amended by S. O. No. 2139 dated 12-8-1972 (Govt. of India Notification No. X. 11014/12/72-D dated the 5th June, 1972).

its expiry, after payment of additional fee, the licence shall continue to be in force until orders are passed on the application and the licence shall be deemed to have expired if application for its renewal is not made within six months after its expiry.

*67-EE. *Certificate of renewal*.—The certificate of renewal of a sale licence in Forms 20-C and 20-D shall be issued in Form 20-E.

6-F. *Condition to be satisfied before a licence in Form 20-C or Form 20-D is granted*.

(1) A licence in Form 20-C or Form 20-D to sell, stock or exhibit for sale or distribute Homoeopathic medicines shall not be granted to any person unless the authority empowered to grant the licence is satisfied that the premises in respect of which the licence is to be granted are clean and in the case of a licence in Form 20-C the sale premises is in charge of a person who is or has been dealing in Homoeopathic medicines and who is in the opinion of the Licensing Authority competent to deal in Homoeopathic medicines.

(2) Any person who is aggrieved by the order passed by the Licensing Authority under sub-rule (1) may within 30 days from the date the receipt of such order appeal to the State Government and the State Government may, after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for representing his case, make such order in relation thereto as it thinks fit.

67-G. *Conditions of licence*.—Licence in Form 20-C or 20-D shall be subject to the conditions stated therein and to the following further conditions, namely :—

- (1) The premises where the Homoeopathic medicines are stocked for sale or sold are maintained in a clean condition.
- (2) The sale of Homoeopathic medicines shall be conducted under the supervision of a person, competent to deal in Homoeopathic medicines.
- (3) The licensee shall permit an Inspector to inspect the premises and furnish such information as he may require for ascertaining whether the provisions of the Act and the Rules made thereunder have been observed.
- (4) The licensee in Form 20-D shall maintain records of purchase and sale of Homoeopathic medicines containing alcohol together with names and addresses of parties to whom sold.
- ** (5) The licensee in Form 20-C shall maintain records of purchase and sale of Homoeopathic medicines containing alcohol. No records of sale in respect of Homoeopathic potentised preparation in containers of 30 ml. or lower capacity and in respect of mother tinctures made up in quantities upto 60 ml. need be maintained.

*Added under Government of India, Ministry of Health, F. P., W.H. and U. D. [Notification No. F. 1-14/67-D, dated the 3rd February, 1969.

**Added under Government of India, Ministry of Health, F. P., W. H. and U. D. Notification No. F. 1-59/68-D, dated the 19th November, 1969.

**67-GG. Additional information to be furnished by an applicant for licence or a licensee to the Licensing Authority :—*

The applicant for the grant of a licence or any person granted a licence under this Part shall, on demand furnish to the Licensing Authority, before the grant of the licence or during the period the licence is in force as the case may be, documentary evidence in respect of the ownership or occupation or rental or other basis of the premises, specified in the application for licence or in the licence granted, constitution of the firm, or any other relevant matter, which may be required for the purpose of verifying the correctness of the statements made by the applicant or the licensee, while applying for or after obtaining the licence, as the case may be.

67-H. Cancellation and suspension of licences—

(1) The Licensing Authority may, after giving the licensee an opportunity to show cause why such an order should not be passed by an order in writing stating the reasons therefor, cancel a licence issued under this Part or suspend it for such period as he thinks fit, if in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or Rules made thereunder :

**Provided that, where such failure or contravention is the consequence of an act or omission on the part of an agent or employees, the licence shall not be cancelled or suspended if the licensee proves to the satisfaction of the Licensing Authority :—*

- (a) that the act or omission was not instigated or connived at by him or, if the licensee is a firm or company, by a partner of the firm or a director of the company, or
- (b) that he or his agent or employee had not been guilty of any similar act or omission within twelve months before the date on which the act or omission in question took place, or where his agent or employee had been guilty of any such act or omission, the licensee had not or could not reasonably have had, knowledge of that previous act or omission, or
- (c) if the act or omission was a continuing act or omission that he had not or could not reasonably have had knowledge of that previous act or omission, or
- (d) that he had used due diligence to ensure that the conditions of the licence or the provisions of the Act or the Rules thereunder were observed.

(2) A licensee whose licence has been suspended or cancelled may, within three months of the date of the order under sub-rule (1), prefer an appeal against that order to the State Government, which shall decide the same.

**Added by S. O. No. 2139 dated 12-8-1972 (Govt. of India Notification X. 11014/12/72-D dated the 5th June, 1972).*

@Amended by G. S. R. No. 926 dated 16/7/1977 (Govt. of India Notification X. 11014/6/ 76-D & M. S. dated 24-6-1977).

PART VII—MANUFACTURE FOR SALE OF DRUGS OTHER THAN HOMOEOPATHIC MEDICINES

68. *Manufacture on more than one set of premises.*—If drugs are **manufactured on more** than one set of **premises** a separate application shall be made and a separate licence shall be issued in respect of each such set of premises.

*69. *Application for licence to manufacture drugs other than those specified in Schedules C and C (1) to the Drugs and Cosmetics Rules.*—

(1) Applications for grant or renewal of licences to manufacture for sale of drugs other than those specified in Schedules C and C(1) shall be made to the licensing authority appointed by the State Government for the purpose of this Part (hereinafter in this Part referred to as the licensing authority) **and shall be made—**

(a) in the case of repacking of drugs for sale or distribution, in Form 24-B; and

(b) in any other case in Form 24.

** (2) Every application in Form 24-B shall be accompanied by a fee of rupees forty and an inspection fee of rupees ten for first inspection or rupees five in the case of inspection for renewal of licences and every application in Form 24 shall be accompanied by a fee of rupees two hundred and an inspection fee of rupees fifty for first inspection or rupees twenty five in the case of inspection for renewal of licences.

** (3) If a person applies for the renewal of a licence after its expiry but within six months of such expiry the fee payable for the renewal of such licence shall be in the case of Form 24-B, rupees twenty per month or part thereof in addition to the **inspection fee** and, in the case of Form 24, rupees two hundred plus an additional fee at the rate of rupees one hundred per month or part thereof in addition to the inspection fee.

(4) A fee of rupees ten and a fee of rupees fifty shall be paid respectively for a duplicate copy of the licence issued under clause (a) and clause (b) of sub-rule (1), if the original is defaced, damaged or lost.

‡ (5) Applications by licensees to manufacture additional items of drugs shall, in the case of a licence to manufacture for sale and distribution other than repacking, be made to the Licensing Authority. Such applications shall, if the additional items of drugs applied for belong to categories is not already included in the licence, be accompanied by a fee of rupees ten for each additional category of drugs specified in Schedule M.

Explanation.—For the purpose of these rules, the term 'repacking' means the process of breaking up any drug from a bulk container into small packages and the labelling of each such package with a view to its sale and distribution, but does not include the compounding or dispensing or the packing of any drug in the ordinary course of the retail business.

*Amended by Government of India Notification No. F. 1-22/59-D, dated 9th April, 1960.

‡Amended by Government of India Notification No. F. 1-60/61-D, dated 17th July, 1962.

**Amended by S. O. No. 2139, dated 12-8-1972 (Govt. of India Notification No. X. 11014/12/72-D dat dthe 5th June, 1972).

***69-A. Loan Licences.** (1) Applications for the grant or renewal of loan licences for the manufacture for sale of drugs other than those specified in Schedule C and C(1) shall be made in Form 24-A to the Licensing Authority and shall be accompanied by a fee of rupees one hundred.

****** Provided that if the applicant applies for the renewal of a licence after its expiry but within six months of such expiry the fee payable for renewal of such licence shall be rupees one hundred plus an additional fee at the rate of rupees fifty per month or part thereof.

Explanation.—For the purpose of this rule a loan licence means a licence which a licensing authority may issue to an applicant who does not have his own arrangements for manufacture but who intends to avail himself of the manufacturing facilities owned by a licensee in Form 25.

(2) The Licensing Authority shall, before the grant of a loan licence, satisfy himself that the manufacturing unit has adequate equipment, staff, capacity for manufacture, and facilities for testing, to undertake the manufacture on behalf of the applicant for a loan licence.

(3) Subject to the provisions of sub-rule (2) application for manufacture of additional items on a loan licence shall be accompanied by a fee of rupees ten for each category of items.

†(4) If the Licensing Authority is satisfied that a loan licence is defaced, damaged or lost or otherwise rendered useless, he may, on payment of a fee of rupees twentyfive issue a duplicate licence.

‡69-B Applications to manufacture 'new drugs' other than the drugs classifiable under Schedules C and C(1) products.

Subject to the other provisions of these Rules.

(i) no 'new drug' shall be manufactured unless it is previously approved by the Licensing Authority mentioned in rule 21 ;

(ii) the manufacturer of a 'new drug' when applying for approval to the Licensing Authority mentioned in sub-rule (i) shall produce all documentary and other evidence relating to its standards of quality, purity and strength and such other information as may be required including the results of therapeutic trials carried out with it;

(iii) while applying for a licence to manufacture a 'new drug' or its preparations an applicant shall produce along with his application evidence that the drug for the manufacture of which application is made has already been approved.

Explanation.—In this rule 'new drug' has the same meaning as in rule 30-A.

***Amended by the Government of India Notification No. F. 1-16/57-D, dated 15th June, 1957.**

†Added under Government of India, Ministry of Health, F. P. and U. D. Notification No. F. 1 -20/64-D, dated the 26th October, 1968.

‡Amended or added under Government of India Notification No. F. 1-19/59-D, dated 13th June, 1961.

****Added by S. O. No. 2139 dated 12-8-1972 (Govt. of India Notification No. X. 11014/12/72-D dated the 5th June, 1972).**

70. *Form of licence to manufacture drugs other than those specified in Schedules C and C(1).*—Licences for repacking of drugs against applications in Form 24-B shall be granted in Form 25-B, and licences for manufacture for sale and distribution against applications in Form 24 shall be granted in Form 25.

*70-A. *Form of loan licence to manufacture for sale of drugs other than those specified in Schedules C and C(1).*—A loan licence to manufacture for sale of drugs other than those specified in Schedules C and C(1) shall be issued in Form 25-A.

†71. *Conditions for the grant or renewal of a licence in Form 25.*—Before a licence in Form 25 is granted or renewed the following conditions shall be complied with by the applicant :—

(1) The manufacture shall be conducted under the active direction and personal supervision of competent technical staff consisting at least of one person who is a whole-time employee and who is—

- (a) a graduate in Pharmacy or Pharmaceutical Chemistry of a University recognised by the Central Government for the purpose of this rule and has had at least eighteen months practical experience after the graduation in the manufacture of drugs. This period of experience may, however, be reduced by six months if the person has undergone training in manufacture of drugs for a period of six months during his University course; or
- (b) a graduate in Science of a University recognised by the Central Government who for the purpose of his degree has studied Chemistry as a principal subject and has had at least three years practical experience in the manufacture of drugs after his graduation; or
- (c) a graduate in Chemical Engineering or Chemical Technology or Medicine of a University recognised by the Central Government with general training and practical experience, extending over a period of not less than three years in the manufacture of drugs, after his graduation; or
- ** (d) holding any foreign qualification the quality and content of training of which are comparable with those prescribed in clause (a), clause (b) or clause (c) and is permitted to work as competent technical staff under this rule by the Central Government :

Provided that any person who was immediately before the 29th June, 1957, actively directing and personally supervising the manufacture of drugs and whose name was accordingly entered in any licence granted in Form 25 as it existed before that date shall be deemed to be qualified for the purposes of this rule.

*Added under the Government of India Notification No. F. 1-16/57-D, dated 15-6-1957 and No. F. 1-22/59-D, dated 9th April, 1960.

**Added under Government of India Notification No. F. 1-19/59-D, dated 13-6-1961.

†Amendment by Government of India Notification No. F. 1-16/57-D, dated 15th June, 1957.

@ Provided further that the Licensing Authority may, in the matter of manufacture of disinfectant fluids, insecticides, liquid paraffin, medicinal gases, non chemical contraceptives, plaster of Paris and surgical dressings, for the manufacture of which the knowledge of Pharmaceutical chemistry or Pharmacy is not essential, permit the manufacture of the substance under the active direction and personal supervision of the competent technical staff, who, although not having any of the qualifications included in clauses (a), (b) or (c) of this rule, has, in the opinion of the Licensing Authority, adequate experience in the manufacture of such substance.

(2) The factory premises shall comply with the conditions prescribed in Schedule M.

(3) The applicant shall provide adequate space, plant and equipment for the manufacturing operations; the space, plant and equipment recommended for various operations are given in Schedule M.

@@(4) The applicant shall provide and maintain adequate staff, premises and laboratory equipment for carrying out tests of the strength, quality and purity of the substances at a testing unit, which shall be separate from the manufacturing unit and the head of the testing unit shall be independent of the head of the manufacturing unit :

Provided that the manufacturing units, which, before the commencement of the Drugs and Cosmetics (Amendment) Rules, 1977, were making arrangements with institutions approved by the Licensing Authority for such tests to be carried out on their behalf may continue such arrangements upto the 30th June, 1977 :

Provided further that for tests requiring sophisticated instrumentation techniques or biological or microbiological methods other than sterility the Licensing Authority may permit such tests to be conducted by institutions approved by it under Part XV(A) of these rules for this purpose.

(5) The applicant shall make adequate arrangements for the storage of drugs manufactured by him.

** (6) The applicant shall, while applying for a licence to manufacture patent or proprietary medicines, furnish to the Licensing Authority evidence and data justifying that the patent or proprietary medicines—

- (i) contain the constituent ingredients in therapeutic/prephylactic quantities as determined in relation to the claims or conditions for which the medicines are recommended for use or claimed to be useful;
- (ii) are safe for use in the context of the vehicles, excipients, additives and pharmaceutical aids used in the formulation and under the conditions in which the formulation for administration and use are recommended;

@ Added under Government of India, Ministry of Health, F. P. and U. D. Notification No. F. 1-14/68-D, dated the 26-10-1968.

@@ Amended by G.S.R. No 926 dated 16-7-1977 (Govt. of India Notification No. X. 11014/6/76-D&MS dated 24-6-1977).

** Added by G. S. R. No. 515 dated 10-4-1976 (Govt. of India Notification No. X. 11013/4/75-D&MS. dated the 24th March, 1976).

- (iii) are stable under the conditions of storage recommended; and
- (iv) contain such ingredients and in such quantities for which there is therapeutic justification.

†71A. *Conditions for the grant or renewal of a licence in Form 25B.*—Before a licence in Form 25-B is granted or renewed the following conditions shall be complied with by the applicant :—

(1) the repacking operation shall be carried out under hygienic conditions and under the supervision of a competent person;

** (2) the factory premises shall comply with the conditions prescribed in Schedule M; and

@ (3) the applicant shall have adequate arrangements in his own premises for carrying out tests for the strength, quality and purity of the drugs at a testing unit which shall be separate from the repacking unit;

Provided that the repacking units, which before the commencement of the Drugs and Cosmetics (Second Amendment) Rules, 1977, were making arrangements with institutions approved by the licensing authority for such tests to be carried out on their behalf, may continue such arrangements upto the 31st July, 1977;

Provided further that for tests requiring sophisticated instrumentation techniques or biological or microbiological methods the licensing authority may permit such test to be conducted by institutions approved by it under Part XV(A) of these rules for this purpose.

Explanation.—A person who satisfies the following minimum qualifications shall be deemed to be a “competent person” for the purposes of rules 71-A or 74-A of these rules, namely :—

- (a) a person who holds the Diploma in Pharmacy approved by the Pharmacy Council of India under the Pharmacy Act, 1948 (VIII of 1948) or a person who is registered under the said Act, or
- (b) a person who has passed the Intermediate examination with Chemistry as one of the principal subjects or an examination equivalent to it or an examination recognised by the Licensing Authority as equivalent to it; or
- (c) a person who has passed the Matriculation examination or an examination recognised by the Licensing Authority as equivalent to it and has had not less than four years practical experience in the manufacture, dispensing or repacking of drugs.

@71-B : *Conditions for the grant or renewal of a licence in Form 25-A* :—Before a licence in Form 25-A is granted or renewed, the applicant

†Added under Government of India Notification No. F. 1-22/59-D, dated 9-4-1960.

**Amended by S. O. No. 2139 dated 12-8-1972 (Govt. of India Notification No. X. 11014/12/72-D dated the 5th June, 1972).

@@Amended by G.S.R. No. 926 dated 16-7-1977 (Govt. of India Notification No. X. 11014/6/76—D&MS dated 24-6-1977.)

@Added by G.S.R. No. 515 dated 10-4-1976 (Govt. of India Notification No. X. 11013/4/75—D&MS dated the 24th March, 1976).

shall, while applying for a licence to manufacture patent or proprietary medicines furnish to the Licensing Authority evidence and data justifying that the patent or proprietary medicines :

- (i) contain the constituent ingredients in therapeutic/prophylactic quantities as determined in relation to the claims or conditions for which the medicines are recommended for use or claimed to be useful;
- (ii) are safe for use in the context of the vehicles, excipients, additives and pharmaceutical aids used in the formulations and under conditions in which the formulations for administration and use are recommended;
- (iii) are stable under the conditions of storage recommended; and
- (iv) contain such ingredients and in such quantities for which there is therapeutic justification.

***72. Duration of licence.**—An original licence or a renewed licence in Form 25 or in Form 25-B unless sooner suspended or cancelled shall be valid up to the 31st December, of the year following the year in which it is granted or renewed.

****Provided** that if the application for the renewal of a licence is made before its expiry, or if the application is made within six months of its expiry, after payment of additional fee, the licence shall continue to be in force until orders are passed on the application and the licence shall be deemed to have expired if the application for its renewal is not made within six months of its expiry.

73. Certificate of renewal.—The certificate of renewal of a licence in Form 25 shall be issued in Form 26.

***73-A. A certificate of renewal of a loan licence.**—The certificate of renewal of a loan licence in Form 25-A shall be issued in Form 26-A.

***73-AA. Duration of loan licence.**—An original loan licence in Form 25-A or a renewed loan licence in Form 26-A, unless sooner suspended or cancelled, shall be valid up to the 31st December, of the year following the year in which it is granted or renewed :

****Provided** that if the application for the renewal of a licence is made before its expiry, or if the application is made within six months of its expiry, after payment of the additional fee, the licence shall continue to be in force until orders are passed on the application and the licence shall be deemed to have expired if the application for its renewal is not made within six months of its expiry.

@73-B. Certificate of renewal of licence in Form 25-B.—The certificate of renewal of a licence in Form 25-B shall be issued in Form 26-B.

*Amended by Government of India Notification No. F. 1-10/62-D, dated 10th April, 1964.

@Added under Government of India Notification No. F. 1-22/59-D, dated 2-4-1961.

**Amended by S. O. No. 2139 dated 12-8-1972 (Govt. of India Notification No. X. 11014/12/72-D dated the 5th June, 1972).

†74. *Conditions of licence in Form 25.*—A licence in Form 25 shall be subject to the conditions stated therein and to the following further conditions, namely :—

- (a) the licensee shall provide and maintain staff, premises and the equipment as specified in rule 71;
- (b) the licensee shall comply with the provisions of the Act and of these Rules and with such further requirements, if any, as may be specified in any rules subsequently made under Chapter IV of the Act; provided that where such further requirements are specified in the rules, these would come into force, four months after publication in the official Gazette;
- (c) the licensee shall either in his own laboratory or in any other laboratory approved by the Licensing Authority under Part XV (A) of these rules test each batch or lot of the raw material used by him for the manufacture of his products and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule U. The records or registers shall be retained for a period of 5 years from the date of manufacture;
- (d) the licensee shall keep records of the details of manufacture as per particulars given in Schedule U of each batch of the drugs manufactured by him and such records shall be retained for a period of five years;
- (e) the licensee shall allow an **Inspector appointed under the Act, to enter, with or without prior notice, any premises and to inspect the plant and the process of manufacture and the means employed in standardising and testing the drugs;
- (f) the licensee shall allow an **Inspector appointed under the Act to inspect all registers and records maintained under these rules and to take samples of the manufactured drugs and shall supply to such Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and the Rules thereunder have been observed;
- (g) the licensee shall, from time to time, report to the Licensing Authority any changes in the expert staff responsible for the manufacture or testing of the drugs and any material alterations in the premises or plant used for the purpose which have been made since the date of the last inspection made on behalf of the licensing authority;
- ** (h) the licensee shall, on request, furnish to the Licensing Authority, the Controlling Authority or to such authorities as the

†Amended by Government of India, Ministry of Health and Family Planning Notification No. F. 1-20/64-D, dated 26th October, 1968.

**Amended by G. S.R. No. 444 dated 28-4-1973 (Govt. of India Notification No. X. 11014/4/72-D (Pt.) dated 31st March, 1973).

Licensing Authority or the Controlling Authority may direct, from every batch, or batches of drugs as the Licensing Authority or the Controlling Authority may from time to time specify, a sample of such quantity as may be considered adequate by such authority for any examination and, if so required, also furnish full protocols of tests which have been applied;

- (i) if the Licensing Authority or the Controlling Authority so directs and if requested by the licensee who had also furnished prima facie reasons for such directions, the licensee shall not sell or offer for sale any batch in respect of which a sample is or protocols are furnished under clause (h) until a certificate authorising the sale of the batch has been issued to him by or on behalf of the Licensing Authority or the Controlling Authority;
- (j) the licensee shall on being informed by the Licensing Authority or the Controlling Authority that any part of any batch of the drug has been found by the Licensing Authority or the Controlling Authority not to conform with the standards of strength, quality or purity specified in these rules and on being directed so to do, withdraw the remainder of the batch from sale, and, so far as may in the particular circumstances of the case be practicable, recall all issues already from that batch;
- (k) the licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed;
- ** (l) the licensee shall maintain reference samples from each batch of the drugs manufactured by him in a quantity which is at least twice the quantity of the drug required to conduct all the tests performed on the batch. In case of drugs bearing an expiry date on the label, the reference samples shall be maintained for a period of three months beyond the date of expiry of potency. In case of drugs where no date of expiry of potency is specified on the label, the reference samples shall be maintained for a period of three years from the date of manufacture.

74-A. *Conditions for licence in Form 25-B.*—A licence in Form 25-B shall be subject to the conditions stated therein and to the following conditions :—

- (a) the repacking of drugs shall at all times be conducted under the personal supervision of at least one person who is approved as a competent person by the Licensing Authority;
- (b) the licensee shall either provide and maintain adequate arrangements in his own premises for carrying out tests of the strength, quality and purity of the drugs repacked or make arrangements with some institution approved by the Licensing Authority under Part XV(A) of these rules for such tests to be regularly carried out on his behalf by the institution;
- (c) the licensee shall make adequate arrangements for the storage of drugs;

- * (d) the licensee shall comply with the provisions of the Act and of these Rules and with such further requirements, if any, as may be specified in any rules subsequently made under Chapter IV of the Act;

Provided that where such further requirements are specified in the rules, these would come into force four months after publication in the Official Gazette.

- (e) the licensee shall allow any Inspector appointed under the Act to enter with or without notice, any premises where the packing of drugs in respect of which the licence is issued is carried on, to inspect the premises and to take samples of repacked drugs;
- * (f) The licensee shall, either in his own laboratory or, in any other laboratory approved by the Licensing Authority, test each batch or lot of raw material used by him for repacking and also each batch of the product thus repacked and shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule U. The records or registers shall be retained for a period of five years from the date of repacking. The licensee shall allow the Inspector to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and these Rules have been observed;
- † (g) the licensee shall maintain an Inspection Book, in Form 35, to enable an Inspector to record his impressions and the defects noticed;
- ** (h) the licensee shall maintain reference samples from each batch of the drugs manufactured by him in a quantity which is at least twice the quantity of the drug required to conduct all the tests performed on the batch. In case of drugs bearing an expiry date on the label, the reference sample shall be maintained for a period of three months beyond the date of expiry of potency. In case of drugs where no date of expiry of potency is specified on the label, the reference samples shall be maintained for a period of three years from the date of manufacture.

*74B. *Conditions of licence in Form 25-A.*—(1) The licence in Form 25-A shall be deemed to be cancelled or suspended, if the licence owned by the licensee in Form 25, whose manufacturing facilities have been availed of by the licensee, is cancelled or suspended, as the case may be, under these rules.

(2) The licensee shall comply with the provisions of the Act and of these Rules and with such further requirements if any, as may be speci-

*Amended by Government of India, Ministry of Health, Family Planning and U. D. Notification No. F. 1-20/64-D, dated the 26th October, 1968.

†Added under Government of India, Ministry of Health, F. P. and U. D. Notification No. 1-14/68-D, dated 26-10-68.

**Added by G. S. R. No. of 444 dated 28-4-1973 (Govt. of India Notification No. X. 11014/4/72-D(Pt.) dated the 31st March, 1973).

ed in any rules subsequently made under Chapter IV of the Act; provided that where such further requirements are specified in the rules, these would come into force four months after publication in the Official Gazette.

(3) The licensee shall test each batch or lot of the raw material used by him for the manufacture of his products and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule U. The records or registers shall be retained for a period of five years from the date of manufacture. The licensee shall allow an Inspector to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and these rules have been observed.

(4) The licensee shall either (i) provide and maintain to the satisfaction of the Licensing Authority adequate staff and adequate laboratory facilities for carrying out tests of the strength, quality and purity of the substances manufactured by him or (ii) make arrangements with some institution approved by the Licensing Authority under Part XV(A) of these rules for such tests to be regularly carried out on his behalf by the institution.

*** (5) The licensee shall maintain reference samples from each batch of the drugs manufactured by him in a quantity which is at least twice the quantity of the drug required to conduct all the tests performed on the batch. In case of drugs bearing an expiry date on the label the reference samples shall be maintained for a period of three months beyond the date of expiry of potency. In case of drugs where no date of expiry of potency is specified on the label, the reference samples shall be maintained for a period of three years from the date of manufacture.

*75. *Form of application for licence to manufacture for sale drugs specified in Schedules C and C(1).*—(1) Applications for the grant or renewal of licences to manufacture for sale drugs specified in Schedules C and C(1) shall be made to the Licensing Authority in Form 27 and shall be accompanied by a fee of rupees three hundred and an inspection fee of rupees two hundred for first inspection or rupees one hundred in the case of inspection for renewal of licences :

**Provided that if the applicant applies for renewal of licence after its expiry but within six months of such expiry, the fee payable for renewal of the licence shall be rupees three hundred plus an additional fee at the rate of rupees two hundred per month in addition to the inspection fee.

(2) A fee of rupees seventy five shall be paid for a duplicate copy of a licence issued under this rule, if the original is defaced, damaged or lost.

(3) Applications by licensees to manufacture additional drugs shall be accompanied by a fee of rupees fifteen for each item listed in the application subject to a maximum of rupees three hundred.

*Added or amended by Government of India Notification No. F. 1-16/57-D, dated 15-6-1961.

**Amended by S. O. No. 2139 dated 12-8-1972 (Govt. of India Notification No. X. 11014/12/72-D, dated the 5th June, 1972).

***Added by G. S. R. No. 444, dated 28-4-1973 (Govt. of India Notification No. X. 11014/14/72-D(Pt.) dated the 31st March, 1973).

***75-A. Loan licences.**—(1) Applications for the grant or renewal of loan licences for the manufacture for sale of drugs specified in Schedules C and C(1) shall be made in Form 27-A to the licensing authority and shall be accompanied by a fee of rupees three hundred.

******Provided that if the applicant applies for the renewal of a licence after its expiry but within six months of such expiry the fee payable for renewal of the licence shall be rupees three hundred plus an additional fee at the rate of rupees two hundred per month or a part thereof.

Explanation.—For the purpose of this rule a loan licence means a licence which a licensing authority may issue to an applicant who does not have his own arrangements for manufacture but who intends to avail himself of the manufacturing facilities owned by another licensee in Form 28.

(2) The licensing authority, shall, before the grant of a loan licence, satisfy himself that the manufacturing unit has adequate equipment, staff, capacity for manufacture and facilities for testing to undertake the manufacture on behalf of the applicant for a loan licence.

(3) Subject to the provisions of sub-rule (2) applications for manufacture of additional items on a loan licence shall be accompanied by a fee of rupees fifteen for each item subject to a maximum of rupees three hundred.

@(4) If the licensing authority is satisfied that a loan licence is defaced, damaged or otherwise rendered useless, he may, on payment of a fee of rupees seventyfive, issue a duplicate licence.

†75-B. Applications to manufacture 'new drugs' classifiable under Schedules C and C(1)—

Subject to the other provisions of these Rules,

- (i) no 'new drug' shall be manufactured unless it is previously approved by the 'Licensing authority' mentioned in rule 21;
- (ii) the manufacturer of a 'new drug' when applying for approval to the licensing authority mentioned in sub-rule (i) shall produce all documentary and other evidence relating to its standards of quality, purity and strength and such other information as may be required including the results of therapeutic trials carried out with it;
- (iii) while applying for a licence to manufacture a 'new drug' or its preparations an applicant shall produce along with his application evidence that the drug for the manufacture of which application is made has already been approved.

Explanation.—In this rule 'new drug' has the same meaning as in rule 30-A.

@Added under Govt. of India, Ministry of Health, F. P., and U. D. Notification No. F. 1-20/64-D, dated the 26-10-1968.

†Added under Govt. of India Notification No. F. 1-19/59-D, dated 13-6-1961.

*Added or amended by Government of India, Notification No. F. 1-16/57-D, dated 15-6-1969.

**Amended by S. O. No. 2139 dated 13-8-1972 (Govt. of India Notification No. X.11014/12/72-D dated the 5th June, 1972).

*76. *Form of licence to manufacture drugs specified in Schedules C and C(1) and conditions for the grant or renewal of such licence.*—A licence to manufacture for sale of drugs specified in Schedules C and C(1) shall be issued in Form 28. Before a licence in Form 28 is granted or renewed the following conditions shall be complied with by the applicant :

(1) The manufacture will be conducted under the active direction and personal supervision of competent technical staff consisting at least of one person who is a whole time employee and who is—

- (a) a graduate in Pharmacy or Pharmaceutical Chemistry of a University recognised by the Central Government for the purpose of this rule and has had at least eighteen months' practical experience after the graduation in the manufacture of drugs to which this licence applies; this period of experience may however be reduced by six months if the person has undergone training in manufacture of drugs to which the licence applies for a period of six months during his University course; or
- (b) a graduate in Science of a University recognised by the Central Government who for the purpose of his degree has studied Chemistry or Microbiology as a principal subject and has had at least three years' practical experience in the manufacture of drugs to which this licence applies after his graduation; or
- (c) a graduate in medicine of a University recognised by the Central Government with at least three years' experience in the manufacture and pharmacological testing of biological products after his graduation; or
- †(d) a graduate in Chemical Engineering of a University recognised by the Central Government with at least three years' practical experience in the manufacture of drugs to which this licence applies after his graduation; or
- (e) holding any foreign qualification the quality and content of training of which are comparable with those prescribed in clause (a), clause (b), clause (c) or clause (d) and is permitted to work as competent technical staff under this rule by the Central Government.

Provided that any person who was approved by the licensing authority as an expert responsible for the manufacture of drugs for the purpose of rule 76 read with rule 78 as these rules were in force immediately before the 29th June, 1957, shall be deemed to be qualified for the purposes of this rule.

@Provided further that for the drugs specified in Schedules C and C(1) meant for veterinary use, the wholetime employee under whose supervision

*Amended or added by Government of India Notification No. F. 1-16/57-D, dated 4-6-1957.

†Amended under Government of India Notification No. F. 1-19/59-D, dated 13-6-1957.

@Added under Govt. of India, Ministry of Health, F. P., W. H. and U. D. Notification No. F. 1-6/62-D, dated 2nd July, 1969.

the manufacture is conducted may be a graduate in Veterinary Science or general science or medicine or pharmacy of a University recognised by the Central Government and who has had at least three years' experience in the manufacture of biological products.

(2) The factory premises shall comply with the conditions prescribed in Schedule M.

(3) The applicant shall provide adequate space, plant and equipment for any or all the manufacturing operations; the space, plant and equipment recommended for various operations are given in Schedule M.

@@(4) The applicant shall provide and maintain adequate staff, premises and laboratory equipment for carrying out such tests of the strength, quality and purity of the substances as may be required to be carried out by him under the provisions of Part X of these rules including proper housing for animals used for the purposes of such tests, the testing unit being separate from the manufacturing unit and the head of the testing unit being independent of the head of the manufacturing unit :

Provided that the manufacturing units which before the commencement of the Drugs and Cosmetics (Amendment) Rules, 1977, were making arrangements with institutions approved by the Licensing Authority for such tests to be carried out on their behalf may continue such arrangements upto the 30th June, 1977 :

Provided further that for tests requiring sophisticated instrumentation techniques or biological or microbiological methods other than sterility the Licensing Authority may permit such tests to be conducted by institutions approved by it under Part XV(A) of these rules for this purpose.

(5) The applicant shall make adequate arrangements for the storage of drugs manufactured by him.

**(6) The applicant shall furnish to the Licensing Authority, if required to do so, data on the stability of drugs which are likely to deteriorate for fixing the date of expiry which shall be printed on the labels of such drugs on the basis of the data so furnished.

*(7) The applicant shall, while applying for licence to manufacture patent or proprietary medicines, furnish to the Licensing Authority evidence and data justifying that the patent or proprietary medicines :—

- (i) contain the constituent ingredients in therapeutic/prophylactic quantities as determined in relation to the claims or conditions for which the medicines are recommended for use or claimed to be useful;

**Added by G. S. R. No. 444 dated 28-4-1973 (Govt. of India Notification No. X. 11014/4/72-D (Pt.) dated 31st March, 1973).

*Added or amended by G. S. R. No. 515 dated 10-4-1976 (Govt. of India Notification No. X. 11013/4/75-D&M.S dated the 24th March, 1976).

@@Amended by G. S. R. No. 926 dated 16-7-1977 (Govt. of India Notification No. X. 11014/6/76-D & MS. dated 24/6/1977).

- (ii) are safe for use in the context of the vehicles, excipients, additives and pharmaceutical aids used in the formulations and under the conditions in which the formulations for administration and use are recommended;
- (iii) are stable under the conditions of storage recommended; and
- (iv) contain such ingredients and in such quantities for which there is therapeutic justification.

***76-A : Form of loan licence to manufacture for sale drugs specified in Schedules C and C(1) and conditions for the grant or renewal of such licence :—**A loan licence to manufacture for sale drugs specified in Schedules C and C(1) shall be issued in Form 28-A, and the applicant shall, while applying for a licence to manufacture patent or proprietary medicines, furnish to the Licensing Authority evidence and data justifying that the patent or proprietary medicines;

- (i) contain the constituent ingredients in therapeutic/prophylactic quantities as determined in relation to the claims or conditions for which the medicines are recommended for use or claimed to be useful;
- (ii) are safe for use in the context of the vehicles, excipients, additives and pharmaceutical aids used in the formulations, and under the conditions in which the formulations for administration and use are recommended;
- (iii) are stable under the conditions of storage recommended; and
- (iv) contain such ingredients and in such quantities for which there is therapeutic justifications.

†77. Duration of licence.—An original licence in Form 28 or a renewed licence in Form 26, unless sooner suspended or cancelled shall be valid up to the 31st December of the year following the year in which it is granted or renewed.

****** Provided that if the application for the renewal of a licence is made before its expiry, or if the application is made within six months of its expiry after payment of additional fee, the licence shall continue to be in force until orders are passed on the application and the licence shall be deemed to have expired if the application for its renewal is not made within six months of its expiry.

@@78. Conditions of licence.—A licence in Form 28 shall be subject to the special conditions, if any, set out in Schedule F or Schedule F(1), as the case may be, which relate to the substance in respect of which the licence is granted and to the following general conditions—

- (a) (i) The licensee shall provide and maintain an adequate staff and adequate premises and plant for the proper manufacture and storage

†Amended under Government of India Notification No. F. 1-10/62-D, dated 10th April, 1964.

@@Amended by Govt. of India, Ministry of Health, F. P., W. H. and U. D. Notification No. F. 1-6/62-D, dated 2nd July, 1969.

**Amended by S. O. No. 2139 dated 12-8-1972 (Govt. of India Notification No. X. 11014/12/72-D, dated the 5th June, 1972).

*Added or Amended by G. S. R. No. 515 dated 10-4-1976 (Govt. of India Notification No. X. 11013/4/75-D & M. S.)

of the substances in respect of which the licence is issued; (ii) without prejudice to the generality of the foregoing requirement, every holder of a licence who for any purpose engaged in the culture or manipulation of pathogenic spore-bearing micro-organisms shall provide to the satisfaction of the Licensing Authority separate laboratories and utensils and apparatus required for the culture or manipulation of such micro-organisms, the laboratories, utensils and apparatus so provided not being used for the manufacture of any other substance;

******(b) The licensee shall provide and maintain staff, premises and equipment as specified in rule 76;

@(c) (i) The licensee shall maintain records of manufacture as per particulars given in Schedule U.

(ii) The licensee shall either in his own laboratory or in any laboratory approved by the Licensing Authority under Part XV(A) of these rules test each batch or lot of the raw material used by him for the manufacture of his product and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule U. The records or registers shall be retained in the case of a substance for which a potency date is fixed for a period of two years from the expiry of such date, and in the case of other substances for a period of five years from the date of manufacture.

(d) The licensee shall allow an *Inspector appointed under the Act to enter, with or without prior notice, any premises where the manufacture is carried on and to inspect the premises, and in the case of substances specified in Schedules C and C(1), to inspect the plant and the process of manufacture and the means employed for standardizing and testing the substance;

(e) The licensee shall allow an *Inspector appointed under the Act, to inspect all registers and records maintained under these rules and to take samples of the manufactured product and shall supply to such Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and Rules thereunder have been observed;

(f) The licensee shall from time to time report to the Licensing Authority any changes in the expert staff responsible for the manufacture or testing of the substance and any material alterations in the premises or plant used for that purpose which have been made since the date of the last inspection made on behalf of the Licensing Authority before the issue of the licence;

*****(g) the licensee shall on request furnish to the Licensing Authority, Controlling Authority or to such authorities as the Licensing Authority or the Controlling Authority may direct, from every batch of drug as the licensing authority or the Controlling Authority may from time to time specify, a sample of such quantity as may be considered adequate by such

@Amended by Govt. of India, Ministry of Health, F. P. and U. D. Notification No. F. 1-20/64-D, dated the 26th October, 1968.

1Amended by G. S. R. No. 444, dated 28-4-1973 (Govt. of India Notification No. X. 11014/4/72-D (Pt), dated the 31st March, 1973).

******Added or amended by Govt. of India Notification No. F-1-16/57-D, dated 15th June, 1957.

authority for any examination and, if so required, also furnish, full protocols of the tests which have been applied.

(h) If the Licensing Authority or the Controlling Authority so directs, the licensee shall not sell or offer for sale any batch in respect of which a sample is, or protocols are furnished under the last preceding sub-paragraph until a certificate authorizing the sale of the batch has been issued to him by or on behalf of the Licensing Authority or the Controlling Authority.

(i) The licensee shall on being informed by the Licensing Authority or the Controlling Authority that any part of any batch of the substance has been found by the Licensing Authority or the Controlling Authority not to conform with the standards of strength, quality or purity specified in these Rules and on being directed so to do, withdraw the remainder of that batch from sale and so far as may in the particular circumstances of the case be practicable recall all issues already made from that batch;

(j) No drug manufactured under the licence shall be sold unless the precautions necessary for preserving its properties have been observed throughout the period after manufacture;

(k) The licensee shall comply with the provisions of the Act and of these rules and with such further requirements, if any, as may be specified in any rules subsequently made under Chapter IV of the Act, provided that where such further requirements are specified in the rules, these would come into force four months after publication in the Official Gazette.

@@(l) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and defects noticed.

*(m) The licensee shall maintain reference samples from each batch of the drugs manufactured by him in a quantity which is at least twice the quantity of the drug required to conduct all the tests performed on the batch. In case of drugs bearing an expiry date on the label, the reference samples shall be maintained for a period of three months beyond the date of expiry of potency. In case of drugs where no date of expiry is specified on the label the reference samples shall be maintained for a period of three years from the date of manufacture.

@@78-A. *Conditions of licence in Form 28-A.*—(1) The licence in Form 28-A shall be deemed to be cancelled or suspended, if the licence owned by the licensee in Form 28 whose manufacturing facilities have been availed of by the licensee is cancelled or suspended, as the case may be, under these rules.

(2) The licensee shall comply with the provisions of the Act, and of these rules and with such further requirements if any, as may be specified in any rules subsequently made under Chapter IV of the Act, provided that where such further requirements are specified in the rules, those would come into force four months after publication in the Official Gazette.

(3) The licensee shall test each batch or lot of the raw material used by him for the manufacture of his products and also each batch of the final product and shall maintain records or registers showing the particulars in

@@Amended by Govt. of India Ministry of Health, F.P. and U.D. Notification No. F.1-14/68-D, dated the 26-10-68.

*Added by G.S.R. No. 444 dated 28-4-1973 (Govt. of India Notification No. X. 11014/4/72-D(Pt.) dated the 31st March, 1973).

respect of such tests as specified in Schedule U. Records or registers shall be retained, in the case of a substance for which a potency date is fixed, for a period of two years from the expiry of such date and in the case of other substances, for a period of five years from the date of manufacture. The licensee shall allow an Inspector to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and these rules have been observed.

(4) The licensee shall either (i) provide and maintain to the satisfaction of the Licensing Authority adequate staff and adequate laboratory facilities for carrying out tests of the strength, quality and purity of the substances manufactured by him or (ii) make arrangements with some institution approved by the Licensing Authority for such tests to be regularly carried out on his behalf by the institution.

*(5) The licensee shall furnish to the Licensing Authority, if required to do so, data on the stability of drugs which are likely to deteriorate for fixing the date of expiry which would be printed on the labels of such drugs on the basis of the data so furnished.

*(6) The licensee shall maintain reference samples from each batch of the drug manufactured by him in a quantity which is at least twice the quantity of the drug required to conduct all the tests performed on the batch. In case of drugs bearing an expiry date on the labels, the reference samples shall be maintained for a period of three months beyond the date of expiry of potency. In case of drugs where no date of expiry of potency is specified on the label, the reference samples shall be maintained for a period of three years from the date of manufacture.

79. *Inspection before grant of licence.*—Before a licence in Form 28 is issued, the Licensing Authority shall cause the establishment in which the manufacture is proposed to be conducted to be inspected by one or more Inspectors appointed by it for the purpose, and the Inspector or Inspectors shall examine all portions of the premises and the plant and appliances, inspect the process of manufacture intended to be employed and the means to be employed for standardizing and testing the substances to be manufactured and enquire into the professional qualifications of the technical staff to be employed.

80. *Report by Inspector.*—The Inspector or Inspectors shall forward to the Licensing Authority a detailed descriptive report of the result of the inspection.

81. *Procedure of Licensing Authority.*—(1) If the Licensing Authority after such further enquiry, if any, as he may consider necessary, is satisfied that the requirements of the Rules under the Act have been complied with and that the conditions of the licence and the Rules under the Act will be observed, he shall issue a licence in Form 28.

(2) If the Licensing Authority is not so satisfied, he shall reject the application and shall inform the applicant of the reasons for such rejection and of the conditions which must be satisfied before a licence can be granted and shall supply the applicant with a copy of the inspection report.

*Added by G.S.R. No. 444 dated 28th April, 1973 (Govt. of India Notification No. X, 11014/4/72-D (Pt.) dated the 31st March, 1973).

*82. *Further application after rejection.*—If within a period of six months from the rejection of an application for a licence the applicant informs the Licensing Authority that the conditions laid down have been satisfied and deposits an inspection fee of rupees fifty the Licensing Authority may, if after causing a further inspection to be made, he is satisfied that the conditions for the grant of a licence have been complied with, issue a licence in Form 28.

83. *Renewal.*—On application being made for renewal, the licensing authority may cause an inspection to be made and, if satisfied that the condition of the licence and the Rules under the Act are, and will continue to be observed, shall issue a certificate of renewal in Form 26.

*83-A. *Certificate of a renewal of a loan licence.*—The certificate of renewal of a loan licence in Form 28-A shall be issued in Form 26-A.

†83-AA. *Duration of loan licence.*—An original loan licence in Form 28-A or a renewed loan licence in Form 26-A, unless sooner suspended or cancelled, shall be valid up to the 31st December, of the year following the year in which it is granted or renewed.

**Provided that if the application for the renewal of a licence is made before its expiry, or if the application is made within six months of its expiry, after payment of the additional fee, the licence shall continue to be in force until orders are passed on the application and the licence shall be deemed to have expired if the application for its renewal is not made within six months of its expiry.

84. The provisions of this Part shall apply to the manufacture of drugs for sale notwithstanding that such drugs are manufactured for sale outside India.

**84-A. *Provision for appeal to the State Government by party whose licence has not been granted or renewed.*

Any person who is aggrieved by the order passed by the Licensing Authority refusing to grant or renew a licence in Form 25, 25-A, 25-B, 26, 26-A, 26-B, 28 and 28-A may within thirty days from the date of receipt of such order, appeal to the State Government and the State Government may, after such enquiry into the matter as it considers necessary and after giving the said person an opportunity for representing his views in the matter, make such order in relation thereto as it thinks fit.

84-AA. *Additional information to be furnished by an applicant for licence or a licensee to the Licensing Authority.*

The application for the grant of a licence or any person granted a licence under this Part shall, on demand, furnish to the Licensing Authority, before the grant of the licence or during the period the licence is in force, as the case may be, documentary evidence in respect of the ownership or occupation rental or other basis of the premises, specified in the application for

*Added or amended by Government of India Notification No. F. 1-16 57-D, dated 15-6 1959.

†Added under Government of India Notification No. F. 1-10/62-D, dated 10th April, 1964.

**Amended or added by S. G. No. 2139 dated 12th August, 1972 (Government of India Notification No. X. 11014/12/72-D, dated the 5th June, 1972).

licence or in the licence granted, constitution of the firm, or any other relevant matter, which may be required for the purpose of verifying the correctness of the statements made by the applicant or the licensee, while applying for or after obtaining the licence, as the case may be.

*****84-B. *Prohibition for the manufacture for sale of cyclamates and preparations containing cyclamates.***

No person shall manufacture for sale cyclamates and preparations containing cyclamates.

85. *Cancellation and suspension of licences.*—(1) The Licensing Authority may, after giving the licensee an opportunity to show cause why such an order should not be passed by an order in writing stating the reason therefor, cancel a licence issued under this Part or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates, if, in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provision of the Act or Rules thereunder.

*(2) A licensee whose licence has been suspended or cancelled may, within three months of the date of the order under sub-rule (1), prefer an appeal against that order to the State Government, which shall decide the same.

‡PART VII-A—MANUFACTURE FOR SALE OF HOMOEOPATHIC MEDICINES

85-A. *Manufacture on more than one set of premises.*—If Homoeopathic medicines are manufactured in more than one set of premises a separate application shall be made and a separate licence shall be obtained in respect of each such set of premises.

85-B. *Application for licence to manufacture Homoeopathic medicines.*—(1) Application for grant or renewal of licences to manufacture for sale of Homoeopathic medicines shall be made to the Licensing Authority appointed by the State Government for the purpose of this Part (hereinafter in this Part referred to as the Licensing Authority) and shall be made in Form 24-C.

**** (2) The application in Form 24-C shall be accompanied—**

- (a) by a fee of rupees forty for the manufacture of Homoeopathic mother tinctures and potentised preparations and an inspection fee of rupees ten for the first inspection or rupees five in case of inspection for renewal of licence;
- (b) by a fee of rupees twenty for the manufacture of Homoeopathic potentised preparations only, and an inspection fee of rupees five for the first inspection or rupees two and fifty paise in case of inspection for renewal of licence;

***Added by S. O. No. 2358 dated 26-8-1972 (Govt. of India Notification No. X. 11014/1/72-D, dated the 21st June, 1972).

‡Added under Government of India Notification No. F. 1-35/64-D, dated 18th August, 1964.

**Amended by G. S. R. No. 245 dated 11-2-1976 (Govt. of India Notification No. X. 11013/5/72-D & M.S. dated the 3rd Feb., 1976).

*Amended by GSR No. 926 dated 16/7/1977 (Govt. of India Notification No. X. 11014/6/76-D&MS dated 24/6/1977)

- (c) by a fee of rupees twenty for the manufacture of potentised preparation from back potencies by pharmacies which are already licensed to sell Homoeopathic medicines by retail and an inspection fee of rupees five for the first inspection or rupees two and fifty paise in case of inspection for renewal of licence.

**** (3)** If a person applies for renewal of a licence after its expiry but within six months of such expiry, the fee payable for the renewal of such a licence shall be—

- (a) rupees forty plus an additional fee at the rate of rupees twenty per month or part thereof and an inspection fee of rupees five for the manufacture of Homoeopathic mother tinctures and potentised preparations;
- (b) rupees twenty plus an additional fee at the rate of rupees ten per month or part thereof and an inspection fee of rupees two and fifty paise for the manufacture of Homoeopathic potentised preparations only;
- (c) rupees twenty plus an additional fee at the rate of rupees ten per month or part thereof and an inspection fee of rupees two and fifty paise for the manufacture of potentised preparations from back potencies by pharmacies who are already licensed to sell Homoeopathic medicines by retail.

(4) A fee of rupees ten shall be paid for a duplicate copy of the licence for the manufacture of Homoeopathic mother tinctures and potentised preparations issued under sub-rule (1) if the original is defaced, damaged or lost. While the fee to be paid for such a duplicate copy of the licence for the manufacture of Homoeopathic potentised preparations only shall be rupees five.

85C. Application to manufacture 'New Homoeopathic medicines'—
Subject to the other provisions of these Rules—

(1) no 'New Homoeopathic medicine' shall be manufactured unless it is previously approved by the Licensing Authority mentioned in rule 21:

(2) the manufacturer of 'New Homoeopathic medicine', when applying to the Licensing Authority mentioned in sub-rule (1) shall produce such documentary and other evidence as may be required by the Licensing Authority for assessing the therapeutic efficacy of the medicine including the minimum provings carried out with it.

(3) While applying for a licence to manufacture a 'New Homoeopathic medicine' an applicant shall produce along with his application evidence that the 'New Homoeopathic medicine' for the manufacture of which application is made has already been approved.

Explanation.—The term 'New Homoeopathic medicine' in this rule shall have the same meaning as in rule 30-AA.

****Amended by G. S. R. No. 245 dated 11th February, 1976 (Govt. of India Notification X. 11013/5/72-D & MS dated the 3rd February, 1976).**

@85-D. Form of licence to manufacture Homoeopathic medicines.— Licence for manufacture of Homoeopathic medicines is a licence to manufacture potentised preparations from back potencies by Pharmacies who are already licensed to sell Homoeopathic medicines by retail and shall be granted in Form 25-C.

85-E. Conditions for the grant or renewal of a licence in Form 25-C.— Before a licence in Form 25-C is granted or renewed the following conditions shall be complied with by the applicant :—

- (1) The manufacture of Homoeopathic medicines shall be conducted under the direction and supervision of competent technical staff consisting at least of one person who is a whole time employee and who has at least five years experience in the manufacture of Homoeopathic medicines.
- @(2) The factory premises shall be clean and the manufacture shall be carried out under hygienic conditions.
- (3) The applicant for manufacture of Homoeopathic mother tinctures shall either (i) provide and maintain adequate staff, premises and laboratory equipment for identifying the raw materials and for testing the mother tinctures wherever possible, or (ii) make arrangements with some institution approved by the Licensing Authority under Part XV(A) of these rules for such tests, wherever possible, to be regularly carried out on his behalf by that institution.
- (4) The premises where Homocopathic medicines are manufactured shall be distinct and separate from the premises used for residential purposes.
- (5) Homoeopathic medicines shall not be manufactured simultaneously with drugs pertaining to other systems of medicine.
- (6) The applicant shall make arrangements for proper storage of Homoeopathic medicines manufactured by him.

@Provided that in case potentised preparations are made in a Pharmacy holding licence in Form 20-C, the conditions (2) and (3) shall not apply. The licensee shall ensure to the satisfaction of the Licensing Authority that the products manufactured by it, conform to the claims made on the label.

*85-F. Duration of licence.—*An original licence or a renewed licence unless it is sooner suspended or cancelled shall be valid upto the 31st December of the year following the year in which it is granted or renewed.

**Provided that if the application for renewal of a licence in force is made before its expiry or if the application is made within six months of its expiry, after payment of additional fee, the licence shall continue to

@Amended by Govt. of India, Min. of Health, F. P., W.H. & U. D. Notification No. F. 1-59/68-D, dated 19th Nov., 1969.

**Amended by S. O. No. 2139 dated 12-8-1972 (Govt. of India Notification No. 11014/12/72-D, dated the 5th June, 1972).

be in force until orders are passed on the application and the licence shall be deemed to have expired if application for its renewal is not made within six months of its expiry.

85-G. Certificate of renewal.—The certificate of renewal of a licence in Form 25-C shall be issued in Form 26-C.

85-H. Conditions of licence.—A licence in Form 25-C shall be subject to the conditions stated therein and to the following further conditions, namely :—

- (a) the licensee shall provide and maintain staff and premises as specified in rule 85-E;
- (b) the licensee shall allow an ***Inspector appointed under the Act to enter, with or without prior notice, any premises where the manufacture of a Homoeopathic medicine in respect of which the licence is issued is carried on, to inspect the premises and to take samples of the manufactured Homoeopathic medicines;
- (c) the licensee shall allow an Inspector to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and the Rules made thereunder have been observed;
- †(d) the licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and defects noticed;
- (e) the licensee shall comply with the following conditions in respect of mother tinctures manufactured by him—
 - (i) the crude drug used in the manufacture of the mother tincture shall be identified and records of such identification shall be kept;
 - (ii) the total solids in the mother tincture shall be determined and records of such tests shall be kept;
 - (iii) the alcohol content in the mother tincture shall be determined and records of the same shall be maintained;
 - (iv) the containers of mother tinctures shall preferably be of glass and shall be clean and free from any sort of impurities or adhering matter. The glass shall be neutral as far as possible;
 - (v) in the process of manufacture of mother tinctures hygienic conditions shall be scrupulously observed by the licensee. Storage and handling conditions shall also be properly observed by the licensee according to Homoeopathic principles.
- (f) records shall be maintained of Homoeopathic medicines containing alcohol and the quantities sold together with names and addresses of parties to whom sold.

***Amended by G. S. R. No. 444 dated 28-4-1973 (Govt. of India Notification No. X. 110/4/72-D(Pt.) dated the 31st March, 1973).

†Amended by Govt. of India, Ministry of Health & F. P.U.D. Notification No. F-1-14/ 68-D, dated 26-10-68.

**85-IH. Additional information to be furnished by an applicant for the licence or a licensee to the Licensing Authority.*

The applicant for the grant of licence or any other person granted a licence under this Part shall, on demand, furnish to the Licensing Authority, before the grant of the licence or during the period the licence is in force, as the case may be, documentary evidence in respect of the ownership or occupation in rental or other basis of the premises, specified in the application for licence or in the licence granted, constitution of the firm or any other relevant matters which may be required for the purpose of verifying the correctness of the statements made by the applicant or the licensee, while applying for or after obtaining the licence, as the case may be.

85-I. Cancellation and suspension of licences.—(1) The Licensing Authority may, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under this Part or suspend if for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates if, in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or Rules made thereunder.

**** (2)** A licensee whose licence has been suspended or cancelled may, within three months of the date of the order under sub-rule (1), prefer an appeal against that order to the State Government, which shall decide the same.

PART VIII—MANUFACTURE FOR EXAMINATION, TEST OR ANALYSIS

86. Conditions relating to manufacture for examination, test or analysis.—The provisions of Section 18 of the Act shall not apply to the manufacture of any drug in small quantities for the purpose of examination, test or analysis if the conditions prescribed in this Part are fulfilled.

87. Labelling.—Any drug manufactured for the purpose of examination, test or analysis shall be kept in containers bearing labels indicating the purpose for which it has been manufactured.

88. Labelling of drugs supplied to other persons.—If any drug manufactured for the purpose of examination, test or analysis is supplied by the manufacturer to any other person, the container shall bear a label on which shall be stated the name and address of the manufacturer, the accepted scientific name of the substance if known, or if not known a reference which will enable the substance to be identified and the purpose for which it has been manufactured.

89. Licence.—If the person proposing to manufacture a drug for the purpose of examination, test or analysis does not hold a licence in Form 25 or Form 28 in respect of such drugs he shall, before commencing such manufacture, obtain a licence in Form 29.

*Added by S.O. No. 2139 dated 12-8-1972 (Govt. of India Notification No. X. 11014/12/72-D, dated the 5th June, 1972).

**Amended by G.S.R. No. 926 dated 16-7-1977 (Govt. of India Notification No. X. 11014/6/76-D&MS dated 24-6-1977).

*Provided that in the case of a drug the composition of which is such that the drug is not generally recognised among experts qualified by scientific training and experience to evaluate the safety of drugs as safe for use, no licence in Form 29 shall be granted unless the applicant produces a certificate from the "Licensing Authority" mentioned in rule 21, to the effect that there would be no objection to such licence being granted.

90. *Form of application.*—(1) An application for a licence in Form 29 shall be made to the Licensing Authority appointed by the State Government for the purposes of this Part (hereafter in this Part referred to as the Licensing Authority) in Form 30 and shall be made by or countersigned by the head of the institution in which, or a director of the firm or company by which, the substance will be manufactured.

*** (2) Every application in Form 29 shall be accompanied by a fee of rupees fifteen.

91. *Duration of licence.*—A licence in Form 29 shall, unless sooner cancelled, be in force for a period of one year from the date of issue, and may thereafter be renewed for periods of one year at a time.

92. *Conditions of licence.*—A licence in Form 25 shall be subject to the following conditions—

- (a) the licensee shall use the drugs manufactured under the licence exclusively for purpose of examination, test or analysis, and shall carry on the manufacture and examination, test or analysis at the place specified in the licence;
- (b) the licensee shall allow any **Inspector appointed under the Act to enter, with or without notice, the premises where the drugs are manufactured and to satisfy himself that only examination, test or analysis work is being conducted;
- (c) the licensee shall keep a record of the quantity of drugs manufactured for examination, test or analysis and of any person or persons to whom the drugs have been supplied;
- (d) the licensee shall comply with such further requirements, if any, applicable to the holders of licences in Form 29 as may be specified in any Rules subsequently made under the Act and of which the Licensing Authority has given him not less than one month's notice;
- (e) the licensee shall maintain an Inspection Book to enable an Inspector to record his impressions and defects noticed.

93. *Cancellation of licences.*—(1) The Licensing Authority may after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under this Part, either wholly or in respect of some of the substances to which it relates, if, in his opinion, the licensee has failed to comply

*Added under Government of India Notification No. F. 1-19/59-D, dated 13-6-1961.

**Amended by G.S.R. No. 444 dated 28-4-1973 (Govt. of India Notification No. 11014/4/72-D(Pt.) dated, 31st March, 1973).

***Added by S.O. No. 903 dated 28-2-1976 (Govt. of India Notification No. X. 11013/2/75-D&MS dated the 10th February, 1976).

with any of the conditions of the licence or with any provision of the Act or Rules thereunder.

*(2) A licensee whose licence has been suspended or cancelled may appeal to the State Government within three months of the date of the order.

PART IX—LABELLING AND PACKING OF DRUGS OTHER THAN HOMOEOPATHIC MEDICINES

94. *Exemption of certain drugs from certain provisions of this Part.*—

(1) Labels on packages or containers of drugs for export shall be adapted to meet the specific requirements of the law of the country to which the drug is to be exported but the following particulars shall appear in a conspicuous position on the innermost container in which the drug is packed and every other covering in which that container is packed :

- (a) name of the drug;
- (b) the name, address of the manufacturer and the number of the licence under which the drug has been manufactured;
- (c) batch or lot number;
- (d) date of expiry, if any.

†(2) The provisions of rules 96 to 101 inclusive, shall not apply to a medicine made up ready for treatment, whether after or without dilution, which is supplied on the prescription of a registered medical practitioner provided that :

(i) the medicine is labelled with the following particulars :—

- (a) The name and address of the supplier;
- (b) The name of the patient and the quantity of the medicine;
- (c) The number representing serial number of the entry in the prescription register;
- (d) The dose, if the medicine is for internal use;
- (e) The words 'FOR EXTERNAL USE ONLY' if the medicine is for external application, and the words "POISON" and "FOR EXTERNAL USE ONLY" in the manner prescribed in rule 98 if the medicine is for external use and contains a substance specified in Schedule E.

(ii) Condition (3) of the conditions in rule 65 is satisfied.

95. *Prohibition of sale or distribution unless labelled.*—Subject to the other provisions of these Rules, no person shall sell or distribute any drug (including a patent or proprietary medicine) unless it is labelled in accordance with these Rules.

*Amended by Government of India, Ministry of Health and F.P., W.H. and U.D. Notification No. F. 1-10-68-D, dated the 17th June, 1969.

†Amended by Government of India Notification No. F. 1-19/59-D, dated 13-6-1961.

*96. *Manner of Labelling* :—(1) Subject to the other provisions of these rules, the following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any drug and on every other covering in which the container is packed, namely :—

(i) The name of the drug

For this purpose, the proper name of the drug shall be given in an equally conspicuous manner as the trade name, if any, and shall be—

- (a) for drugs included in Schedule F or Schedule F(1), the name given therein;
- (a) for drugs included in Schedule F or Schedule F(1), the official pharmacopoeias and official compendia of drug standards prescribed in rule 124, the name or synonym specified in the respective official pharmacopoeias and official compendia of drug standards followed by the letters 'I.P.' or, as the case may be by the recognised abbreviations of the respective official pharmacopoeias and official compendia of drug standards;
- (c) for drugs included in the National Formulary of India, the name or synonym specified therein followed by the letters 'N.F.I.';
- (d) for other drugs, the international non-proprietary name, if any, published by the World Health Organisation or where an international non proprietary name is not published, the name descriptive of the true nature or origin of the substance;

(ii) A correct statement of the net content in terms of weight, measure, volume, number of units of contents, number of units of activity, as the case may be, and the weight, measure and volume shall be expressed in Metric system;

(iii) The content of active ingredients.

This shall be expressed —

- (a) for oral liquid preparations in terms of the content per single dose, the dose being indicated in 5 millilitres or multiple thereof :

Provided that where the dose is below 5 millilitres the contents of active ingredients may be expressed in terms of one millilitre;

- (b) for liquid parenteral preparations ready for administration in terms of 1 millilitre or percentage by volume or per dose in the case of a single dose container :

Provided that if the preparation is contained in an ampoule it will be enough if the composition is shown on the label

or wrapper affixed to any package in which such ampoule is issued for sale:

- (c) for drugs in solid form intended for parenteral administration, in terms of units or weight per milligramme or gramme;
- (d) for tablets, capsules, pills and the like, in terms of the content in each tablet, capsule, pill or other unit, as the case may be;
- (e) for other preparations, in terms of percentage by weight or volume or in terms of unitage per gram or millilitre, as the case may be :

Provided that clause (iii) shall not apply to pharmacopoeial preparation where the composition of such preparation is specified in the respective pharmacopoeia and to a preparation included in the National Formulary of India;

- (iv) The name and address of the manufacturer :

Provided that if the drug is contained in an ampoule or a similar small container, it shall be enough if only the name of the manufacturer and his principal place of business is shown;

- (v) A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figure representing the batch number being preceded by the words 'Batch No.' or 'B. No.' or 'Batch' or 'Lot No.' or 'Lot';

NOTE

- (1) In the case of drugs manufactured by a continuous process, like manufacture of magnesium sulphate, pharmaceutical chemicals etc., the production resulting in one homogeneous mix of the finished products shall be considered as one "Batch".
- (2) In the case of powders, liquid orals, ointments, etc., one "Batch Number" shall be assigned to all the containers filled from one homogeneous bulk.
- (3) In the case of tablets, capsules, lozenges, troches, etc. one "Batch Number" shall be assigned to the products manufactured from one homogeneous mix ready for compression or filling.
- (4) In the case of parenteral preparations sterilized by steam under pressure, one "Batch Number" shall be assigned to all containers filled from one homogeneous bulk solution and sterilized in one sterilizer load.
- (5) In the case of containers of parenteral preparations filled from one homogeneous bulk solution and sterilized in more than one sterilizer load, the "Batch Number" assigned to the containers in the different sterilizer loads shall be the same "Batch Number" as is assigned to the homogeneous bulk solution, provided

the samples taken from all the sterilizer loads pass the sterility test, and are kept separate from one another until the report of the sterility test is available.

EXPLANATION :—For the purpose of chemical and other tests, representative samples from all containers filled from the homogeneous bulk solution should be taken.

- (6) In the case of parenteral and other sterile products filled aseptically, a "Batch Number" shall be assigned to all containers filled from one homogeneous mix during one filling operation, the filling operation being completed in a period of not more than a day and during which no schedule change in the filling assembly is made.

When containers are filled from one homogeneous mix, in a number of filling operations, the "Batch Number" assigned to the containers filled in individual filling operations shall be the same "Batch Number" as is assigned to the homogeneous mix, provided the samples taken from all the different filling operations pass the sterility tests, and are kept separate from one another until the report of the sterility test is available.

EXPLANATION—For the purpose of chemical and other tests, representative samples from all containers filled from the homogeneous mix should be taken.

- (7) In the case of medicinal gases produced by a continuous process of operation a week's production from one tank load shall be considered as a Batch :
- (vi) Every drug manufactured in India shall bear on its label the number of the licence under which the drug is manufactured, the figure representing the manufacturing licence number being preceded by the words "Manufacturing Licence Number" or "Mfg. Lic. No." or "M.L.";
- (vii) Drugs specified in Schedule P and their preparations including combinations with other drugs shall bear on their labels the date of manufacture, and the date of expiry of potency, and the period between the date of manufacture and the date of expiry shall not exceed that laid down in the said Schedule under the conditions of storage notified by the Licensing Authority specified in sub-rule (1) of rule 59;

Provided that this period may be extended by the Licensing Authority specified in clause (b) of rule 21 in respect of any specified drug if satisfactory evidence is produced by the manufacturer to justify such an extension;

Drugs specified in Schedule C(1) and their preparations including combinations with other drugs shall bear on the labels (a) the date of manufacture, (b) date of expiry of potency fixed by the manufacturer, and (c) where such drugs are imported, also the number of licence under which the drug is imported, preceded by the words "Import Licence".

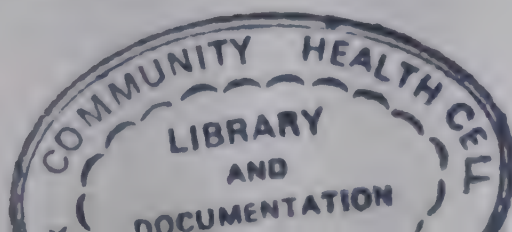
Provided that no reference shall be made to any other licence number granted by any authority outside India on any label or container or in any covering in which the container is packed or in any other matter or advertisement enclosed therewith;

- (ix) Every drug intended for distribution to the medical profession as a free sample shall, while complying with the labelling provisions under clauses (i) to (viii), further bear on the label of the container the words 'Physician's Sample—Not to be sold' which shall be overprinted.
- (2) (i) The particulars to be printed or written on the label of a mechanical contraceptive shall be as specified in Schedule R.
- (ii) The following particulars, in addition to those specified under sub-rule (1) shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container and on every other covering in which the container of a contraceptive, other than a mechanical contraceptive, is packed, namely :—
- (a) the date of manufacture;
- (b) the date upto which the contraceptive is expected to retain its properties;
- (c) the storage conditions necessary for preserving the properties of the contraceptive upto the date indicated in sub-clause (b) :

Provided that for oral contraceptives it shall be sufficient to display on the label of the container the date of manufacture only.

- (3) (i) The particulars prescribed in sub-rule (1) shall be printed or written in indelible ink either on the label borne by a container of vaccine lymph or on a label or wrapper affixed to any package in which the container is issued for sale. The said particulars shall be indelibly marked on the sealed container of surgical ligature or suture or printed or written in indelible ink on a label enclosed therein.
- (ii) Nothing in these rules shall be deemed to require the labelling of any transparent cover or of any wrapper, case or other covering used solely for the purpose of packing, transport or delivery.
- (4) Where by any provision of these rules any particulars are required to be displayed on a label on the container, such particulars may, instead of being displayed on a label, be etched, painted or otherwise indelibly marked on the container :

Provided that, except where otherwise provided in these rules, the name of the drug or any distinctive letters intended to refer to the drug shall not be etched, painted or otherwise indelibly marked on any glass container other than ampoules.



Explanation :—For the purpose of this rule, the date of expiry shall be in terms of month and year and it shall mean that the drug is recommended till the last day of the month. The date of expiry shall be preceded by the words 'Expiry date'.

97. *Labelling of medicines*.—(1) The container of a medicine for internal use made up ready for the treatment of human ailments shall—

- (a) If it contains a substance specified in Schedule E, and not specified in Schedule G, be labelled with the word "Poison";
- (b) If it contains a substance specified in Schedule G, be labelled with the words "Caution. It is dangerous to take this preparation except under medical supervision".
- *(c) If it contains a substance specified in Schedule H, it shall be labelled with the words :

SCHEDULE H DRUG

"Warning—To be sold by a retailer on the prescription of a Registered Medical Practitioner only."

- †(d) If it contains a substance specified in column 1 of Schedule E in a strength below that specified in column 2 thereof, be labelled with the words :—

"Caution.—It is dangerous to exceed the stated dose".

- (c) If it contains a substance specified in Schedule H, it shall be led with the words :—

SCHEDULE L DRUG

"Warning—To be sold by a retailer on the prescription of a Registered Medical Practitioner only".

‡ (2) The container of a embrocation, liniment, lotion, liquid antiseptic or other liquid medicine for external application, which is made up ready for the treatment of human ailments, shall be labelled with the words "For external use only". If the medicine contains a substance specified in Schedule E, the container shall be labelled with the words "Poison. For external use only".

@(3) The container of a medicine made up ready only for treatment of an animal shall be labelled conspicuously with the words 'Not for human use; for animal treatment only' and shall bear a symbol depicting the head of a domestic animal.

(4) The container of a medicine which is not made up ready for treatment shall, if the medicine contains a substance specified in Schedule E, be labelled with the word "Poison".

*Added under Government of India Notification No. F. 10-23/49-D. S., dated 4-11-1952.

†Added under Government of India Notification No. F. 1-63/61-D dated 17th July, 1963.

‡Amended by Government of India Notification No. F. 1-63/61-D, dated 17th July, 1963.

@Amended by Govt. of India Ministry of Health, F. P., W. H. and U. D. Notification No. F.1-6/62-D, dated 2-7-1969.

Explanation.—A medicine shall be deemed to be made up ready for treatment if it is made up and labelled with a dose ready for use, whether after or without dilution.

(5) The container of a medicine prepared for treatment of human ailments shall if the medicine contains industrial methylated spirit, indicate this fact on the label and be labelled with the words :—

‘For External Use only’.

98. *Manner of labelling.*—The words with which a container of a medicine is required to be labelled under Rule 97 shall—

- (a) if the medicine contains a substance specified in Schedule E either be in red lettering or be set against a red background, and
- (b) in all cases shall be on a separate label or be surrounded, by a line within which there shall be no other words except words with which the container is required to be labelled under these Rules.

99. *Labelling with the name and address of seller.*—The container of any substance specified in Schedule E, or preparation containing such substance shall be labelled with the name and address of the seller and the address of the premises on which it was sold :

Provided, that when the substance or preparation is sold in a container and outer covering, it shall be sufficient if the name and address of the seller appears either on the container or on the outer covering :

Provided further that when the substance or preparation is supplied from a warehouse or depot in the course of wholesale dealing it shall be sufficient if the container is labelled with the seller's principal place of business.

100. *Labelling with the name of substance specified in Schedule E*—
(1) Subject to the provisions of this Rule, the container of any substance specified in Schedule E, or preparation containing such substance shall be labelled with the name of such substance.

(2) For the purpose of this Rule, the name of a substance shall be the term under which it is included in Schedule E :

Provided that, where the said term describes a group of substances and not the substance specifically, the name of the substance shall be—

- * (a) if the preparation is included in the Indian Pharmacopocia, the name or synonym set out therein, or
- * (b) if the preparation is not included in Indian Pharmacopocia, the international non-proprietary name of the drug, if any, published

*Amended by under G. S. R. No. 19 dt. 7-1-1978 (Govt. of India Notification No. X. 11013/1/77-D&MS, dated 15-12-1977.

by the World Health Organisation, or where an international non-proprietary name is not published the name descriptive of the true nature or origin of the substance.

- ** (3)** In the case of a preparation included in the Indian Pharmacopoeia, it shall be sufficient, notwithstanding anything in the foregoing sub-rule, to state the name or synonym used to describe the preparation in the Indian Pharmacopoeia, with the addition of the letters 'I.P.'.

101. Labelling with the statement of quantity of alcohol or a substance specified in Schedule E. (1) Subject to the provisions of this Rule, the label of the container of any preparation containing not less than 3 per cent by volume of alcohol, or a substance specified in Schedule E, shall include a statement of the quantity of alcohol or of the said substance contained in the preparation as hereafter provided.

(2) If the preparation contains alcohol, the quantity of alcohol shall be stated in terms of the average percentage by volume of absolute alcohol in the finished product.

***(3)** If the preparation contains a substance specified in Schedule E, the quantity of the substance so specified shall be stated in a manner laid down in Rule 96.

(4) In the case of a preparation containing a substance specified in Schedule I, it shall be sufficient to state on the label the particulars specified in that Schedule.

**** (5)** In the case of a preparation included in the Indian Pharmacopoeia if the container is labelled with the name used to describe the article in the Indian Pharmacopoeia with the addition of the letters 'I.P.' it shall not be necessary to state on the label the proportion of the substance specified in Schedule E contained in the preparation.

‡102. Non-Sterile Surgical Ligature and Suture.—Every container of, and wrapper enclosing surgical ligature or suture other than a ligature or suture offered or intended to be offered for sale as sterile, shall bear a label on which are printed or written in a conspicuous manner in indelible red ink the words "Non-sterile surgical ligature (suture)—not to be used for operations upon the human body unless efficiently sterilized".

103§ (1)

*Amended by Government of India Notification No. F. 1-63/61-D, dated 17th July 1963.

‡Amended by Government of India Notification No. F. 1-3/51-D. S., dated 15-10-54.

§Omitted by Government of India Notification No. F. 1-16/57-D, dated 6-6-1957.

**Amended under GSR. No. 19 dated 7-1-1978 (Govt. of India Notification No. X. 11013-/1/77- D&MS, dated the 15-12-77

(2) The name and address of the manufacturer shall be printed on the label of the container of a patent or proprietary medicine.

£(3) The true formula or list of ingredients shall be printed or written in indelible ink on the outer label of every package containing patent or proprietary medicine.

*104. *Use of Letters I.P. etc.*—The letters 'I.P.' and recognised abbreviations of pharmacopoeias and official compendia of drug standards prescribed under these rules shall be entered on the label of the drug only for the purpose of indicating that the drug is in accordance with standards set out in the Indian Pharmacopoeia or in any such pharmacopoeia or official compendium of drug standards recognised under the Rules.

*105. *Packing of drugs.*—Drugs intended for retail sale shall be packed in containers meant for such sale.

†106. *Diseases which a drug may not purport to prevent or cure.*—(1) No drug may purport or claim to prevent or cure or may convey to the intending user thereof any idea that it may prevent or cure one or more of the diseases or ailments specified in Schedule J.

(2) No drug may purport or claim to procure or assist to procure, or may convey to the intending user thereof any idea that it may procure or assist to procure, miscarriage in women.

‡*Explanation.*—For the purpose of the rules in this Part, a substance specified in Scheduled E shall mean a substance specified in column 1 thereof and its preparations excluding the substance and its preparations exempted under column 2 or 3 thereof.

§PART IX-A.—LABELLING AND PACKING OF HOMOEOPATHIC MEDICINES

106-A. *Manner of labelling of Homoeopathic medicines.*—(A) The following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any Homoeopathic medicine and on every other covering in which the container is packed—

- (i) The words 'Homoeopathic medicine',
- (ii) the name of the medicine—
 - (a) For drugs included in the Homoeopathic Pharmacopoeias of the United States or the United Kingdom, the name specified in that Pharmacopoeia.
 - (b) For other drugs, the name descriptive of the true nature of the drug.

£Amended by Government of India Notification No. F. 1-16/57-D, dated 15-6-57.

†Amended by Government of India Notification No. F. 1-16/52-DS, dated 22-6-1954.

§Added under Government of India Notification No. F. 1-63/61-D, dated 17th July, 1963.

§Added under Government of India Notification No. F. 1-35/64-D, dated 18th August, 1964.

*Amended by G.S.R. No. 19 dated 7-1-1978 Government of India Notification No. X.1 1013/1/77-D& MS dated 15-12-77

- (iii) The potency of the Homoeopathic medicine—For this purpose the potency shall be expressed either in decimal, centesimal or millesimal systems.
- @(iv) Name and address of the manufacturer when sold in original containers of the manufacturer. In case a Homoeopathic medicine is sold in a container other than that of the manufacturer—the name and address of the seller.
- (v) In case the Homoeopathic medicine contains alcohol, the alcohol content in percentage by volume in terms of ethyl alcohol shall be stated on the label.

Provided that in case the total quantity of the Homoeopathic medicine in the container is 30 millilitre or less it will not be necessary to state the content of alcohol on the label.

(B) In addition to the above particulars the label of a Homoeopathic mother tincture shall display the following particulars :—

- (i) a distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figures representing the batch number being preceded by the words "Batch No." or "Batch" or "Lot Number" or "Lot No." or "Lot" or any distinguishing prefix.
- (ii) manufacturing licence number, the number being preceded by the words "Manufacturing Licence Number" or "Mfg. Lic. No." or "M.L."

****Explanation :—**This clause shall not apply to a Homoeopathic mother tincture manufactured outside India.

(C) No Homoeopathic medicine containing a single ingredient shall bear a proprietary name on its label.

PART X—SPECIAL PROVISIONS RELATING TO BIOLOGICAL AND OTHER SPECIAL PRODUCTS

***107. Name of substance.**—If any substance specified in Schedule C is advertised or sold as a proprietary medicine or is contained in a medicine so advertised or sold, the proper name of the substance shall appear on the label in the manner prescribed in this Part.

†Explanation :—For the purpose of this rule the expression "Proper name" means the proper name stated in Schedule F or if no such name is stated, the name descriptive of the true nature and origin of the substance. Provided that in the case of veterinary biological product the expression "proper name" means the proper name stated in Schedule F(I) or if no such name is stated, the name or synonym given in the current edition for the

@Amended by Govt. of India, Min. of Health F.P.W.H. & U.D. Notification No. F. 1-59/68-D dated 19-11-1969.

*Amended by Government of India Notification No. F. 1-5/47-D, dated 25-11-1949.

†Amended by Govt. of India, Ministry of Health, F. P. W. H. and U. D. Notification No. F. 1-6/62-D, dated 2-7-69.

**Added by S. O. No. 2139 dated 12-8-1972 (Government of India Notification No. X-11014/12/72-D, dated the 5th June, 1972).

time being of the British Veterinary Codex, or, if no such name is stated either in Schedule F(1) or the British Veterinary Codex, the name descriptive of the true nature and origin of the substance approved by the Licensing Authority.

108. *Container*.—*(1) No substance specified in Schedule C shall be sold or offered for sale unless it has been sealed in a previously sterilised container made of glass or any other suitable material approved for the purpose by the Licensing Authority appointed under rule 21, in such manner as may, in the opinion of the Licensing Authority, suffice to preclude the access of bacteria.

Provided that it shall not be necessary to use a previously sterilised container if the filled and sealed container is to be sterilised after the sealing and such sterilising procedure would render the product sterile. However, the Licensing Authority may, for any special reasons, direct the licensee to pre-sterilise such containers.

(2) When any such substance is issued in liquid form in containers which are sealed in such a manner that portions of the contents can be withdrawn for use on different occasions, the liquid shall contain a sufficient proportion of some antiseptic to prevent the growth of any organism which may be accidentally introduced in the process of removing a portion of the contents of the container.

Provided that nothing in this sub-rule shall apply to a penicillin suspension in oil and wax.

@(3) The container shall comply with such further requirements, if any, as are specified in Schedule F or Schedule F(1) as the case may be, in that behalf.

@(4) The Licensing Authority may in the case of any particular preparation of any such substance dispense with any of the requirements of this Rule or Schedule F or Schedule F(1) as the case may be, and may make such additional requirements, as having regard to the nature of the preparation, they may deem necessary.

****109-Labelling-**(1) The following particulars and such further particulars, if any, as are specified in Schedule F or Schedule F(1), as the case may be, shall be printed or written in indelible ink on the label of every phial, ampoule or other container of a substance specified in Schedule C and on every other covering in which such phial, ampoule or container is packed—

- (a) where a drug is imported, the number of licence under which it is imported, preceded by the words 'Import Licence' :

Provided that no reference shall be made to any other import licence number granted by any authority outside India on any label or container or in any covering in which the container is

*Amended by G. S. R. No. 245 dated 21-2-1976 (Govt. of India Notification No. 11013/5/72-D&MS, dated 3-2-1976).

@Amended by Govt. of India, Ministry of Health, F.P., W.H. and U.D. Notification No. F.1-6/62-D, dated 2-7-1969.

**Amended by G.S.R. No. 19 dated 7/1/1978 (Govt. of India Notification No. X-11013/1/77-D&MS dated 15/12/1977).

packed or in any other matter of advertisement enclosed therein

- (b) where a test for potency in units is required by these rules, a statement of the potency in units defined in terms of relation to the standard preparation specified in Schedule F or F(1), as the case may be :

Provided that this clause shall not apply in the case of vaccine lymph.

- (c) where a test for potency or maximum toxicity is required the date upto which the substance if kept under suitable conditions may be expected to retain a potency not less than that stated on the label of the container or not to acquire a toxicity greater than that permitted by the test, as the case may be. The date of expiry shall be in terms of month and year and it shall mean that the drug is recommended for use till the last day of the month. The date of expiry shall be preceded by the words 'Expiry date' :

Provided that nothing in these rules shall be deemed to require the labelling of any transparent cover or any wrapper, case or other covering used solely for the purpose of packing, transport or delivery.

(2) The particulars prescribed in clause (a) of the preceding sub-rule shall be printed or written in indelible ink either on the label borne by a container of vaccine lymph or on a label or wrapper affixed to any package in which the container is issued for sale. The said particulars shall be indelibly marked on the sealed container of surgical ligature or suture or printed or written in indelible ink on a label enclosed therein.

(3) The following particulars, and such further particulars, if any, as are specified in Schedule F or Schedule F(1), as the case may be, shall be printed or written in indelible ink either on the label borne by the container of any substance specified in Schedule C or on a label or wrapper affixed to any package in which any such container is issued for sale, namely :—

- (a) the date on which the manufacture of the particular batch from which the substance in the container is taken was completed as defined in Schedule F or Schedule F(1) or if there is no definition in Schedule F or Schedule F(1) as hereafter defined in this rule and in the case of vaccine prepared from concentrates, the date of completion of the final products and the bottling for issue;
- (b) where an antiseptic substance has been added, the nature and the percentage proportion introduced;
- (c) the precaution necessary for preserving the properties of the contents up to the date indicated in clause (c) of sub-rule (1).

(4) For the purpose of clause (a) of sub-rule (3), the date on which the manufacture of a batch is completed shall be—

- (a) in cases where a test for potency or toxicity is required by these rules or not being so required, is accepted by the Licensing Authority as sufficient for the purpose of fixing the date of completion of manufacture, the date on which the substance was removed from cold storage after having been kept at a tempera-

ture not exceeding 5°C continuously for a period not exceeding two years from the time when the last test was completed ;

- (b) in cases where no such test is required or accepted;
 - (i) if the substance is a serum obtained from a living animal, the earliest date on which any material contributing to the batch was removed from the animal;
 - (ii) if the substance was obtained by the growth of organisms on artificial media, the earliest date on which growth was terminated in any of the material contributing to the batch :

Provided that if a batch of the substance (including all material contributing to this batch) has for a period of not more than three years been kept in cold storage at a temperature not exceeding 5°C continuously from the earliest practicable date after that on which growth was terminated in the material as the case may be, the date of removal from cold storage shall be treated as the date on which the manufacture of the batch is completed;

- (c) in all other cases, the date on which the substance is filled in the container.

110. *Prohibition of sale of substance after prescribed date.*—No person shall sell, or exhibit for sale any substance specified in Schedule C after the date recorded on the container, label or wrapper as the date upto which the substance may be expected to retain a potency not less than, or not to acquire a toxicity greater than that required or permitted by the prescribed test as the case may be.

*110-A. *Prohibition against altering inscriptions on containers, labels or wrappers of drugs.*—No person shall alter, obliterate or deface any inscription or mark made or recorded by the manufacturer on the container, label or wrapper of any drug;

Provided that nothing in this rule shall apply to any alteration of any inscription or mark made on the container, label or wrapper of any drug at the instance or direction or with the permission of the Licensing Authority.

@111. *Standards.*—Every substance specified in Schedule C and C(I) intended for sale shall conform with the standards of strength, quality and purity specified in these Rules and in Schedule F or F(1), as the case may be, and the tests for determining such conformity shall be applied to samples taken from the final product after every manufacturing process has been completed.

@112. *Tests for strength and quality.*—The tests, if any, required for determining the strength and quality of each of the substances specified in Schedules C and C(I) shall be those set out in Schedule F or Schedule F(1) as the case may be.

113. *Tests for sterility.*—The test for sterility in the case of surgical ligature or suture shall be that prescribed in Part X of Schedule F.

*Added under Government of India Notification No. F. 1-5/53-DS, dated 17-1-1955.

@Amended by Govt. of India, Ministry of Health, F.P., W.H. and U.D. Notification No. F. 1-6/62-D, dated 2-7-1969.

114. The following tests for the presence of living aerobic or anaerobic bacteria shall be made by the manufacturer or by some institution approved by the Licensing Authority for the purpose of carrying out test on his behalf in the case of—

- (a) sera and solutions of serum proteins intended for injection;
- (b) the bacterial vaccine to which Part I(A) of Schedule F applies;
- (c) carbonised antirabic vaccine;
- (d) toxins, antigens and mixtures of toxins or antigens with serum which are intended to be used in medical practice for immunizing treatment or for diagnosis by inoculation of the patient;
- (e) solution and suspensions of insulin;
- (f) dry preparations of insulin intended for therapeutic use;
- (g) preparations of the posterior lobe of the pituitary body intended for use by injection;
- (h) any other preparations in a form to be administered parenterally;
- †(i) preparation from cultures of pathogenic organisms in a form to be administered orally, which must be sterile :

Provided that (i) in the case of dry preparations of insulin the tests shall be applied with such modifications as the Licensing Authority considers appropriate; and (ii) if a manufacturer satisfies the Licensing Authority that he has already in use tests for the presence of living aerobic or anaerobic bacteria in any of the above named substances, and that these tests, as applied by him will detect the presence of such bacteria in the substance as ready for issue with a certainty at least equal to that afforded by the application of the tests prescribed by this Part, the Licensing Authority may approve the use of such tests in the place of the prescribed tests, that in such a case the authority may at any time withdraw such approval and require the manufacturer to carry out the prescribed tests.

115. *Application of tests for sterility*—The tests shall be applied—

- (a) to samples taken from each batch of the substance before the operation of filling and sealing the containers in which it is to be issued has commenced except preparations, which after being sealed in the containers are to be sterilized by heat, in a manner satisfactory to the Licensing Authority; and
- (b) to the contents of sample containers when ready for issue.

116. *Amount of samples*—The samples required to be taken under the last preceding Rule shall be taken in the following proportions—

- (a) in the case of samples taken from the batch, the quantity taken shall be not less than 0.1 per cent of the total volume of the batch if the volume is not more than 10 litres, and not less than 10 c.c. if the volume is 10 litres or more, but shall in no case be less than 1 c.c. :

Provided that if at the time when the test is made, the batch is contained in a number of bulk containers samples in the foregoing

†Added under Government of India Notification No. 18-1/46-D dt. 18-6-48.

proportions shall be taken from each of such bulk containers and be separately tested;

- (b) in the case of the contents of sample containers the number of containers taken for test shall be not less than 1 per cent of total number filled from the batch, if this number is not more than 1,000, and not less than 10 containers if the total number is more than 1,000.

117. *Method of preparing and using media*—(1) The tests shall be made on fluid media, the quantity of medium contained in each tube or other vessel used in the test being such as to secure that any phenolic antiseptic present in the samples is diluted to less than 0.01 per cent.

When an antiseptic other than a phenolic antiseptic is used the dilution to be employed shall be that approved by the Licensing Authority.

(2) In the case of a test for aerobic organisms the medium shall consist either of a meat extract with the addition of 1 per cent of peptone, or of such an equivalent as can be prepared by the tryptic digestion of muscle or any other medium approved by the Licensing Authority. After the final sterilization the hydrogen-ion concentration of the medium shall be between the limits represented by $\text{pH}=7.2$ and $\text{pH}=7.8$.

(3) In the case of a test for anaerobic organisms, the medium shall consist of a nutrient broth similar to that used in testing for aerobic organism, with the addition of heat coagulated muscle of an amount sufficient to occupy a depth of not less than one centimetre at the bottom of the tube. After the final sterilization the hydrogen-ion concentration of the medium shall be between the limits represented by $\text{pH}=7.2$ and $\text{pH}=7.8$. Before the test inoculation the medium shall be heated to 100°C for a period sufficient to free it completely from dissolved oxygen, and then be cooled to 37°C or lower.

(4) The Licensing Authority may, at the request of any licensee, authorize the use, for the test prescribed under either sub-rule (2) or (3) of this Rule, of any other specified medium or method of using a specified medium on being satisfied that its use affords equal certainty in the detection of the presence of living aerobic or anaerobic organisms, as the case may be.

118. *Method of testing*—(1) In the case of samples taken from the batch each sample shall be inoculated into tubes or other vessels containing the media, one-half of the total volume of the sample being used for the aerobic and one-half for the anaerobic test.

(2) In the case of the contents of sample containers the contents of each container shall be subjected to the test for aerobic and the test for anaerobic organisms. When the volume in the container is 2 c.c. or more, 1 c.c. shall be used for each test. When the volume in the container is less than 2 c.c. the contents shall be divided into two approximately equal parts, one part being used for the aerobic and the other for the anaerobic test.

(3) The inoculated tubes shall be incubated at 37°C for five days and be examined after incubation, permanent records being kept of the examination of each tube.

119. (1) If at this examination no growth of micro-organisms is found in any tube, the sample may be treated as having passed the test.

(2) If at the examination a growth of micro-organisms is visible, further samples may be taken and the tests may be repeated on the further samples taken; but no container the contents of which form part of the batch shall be issued until such further samples have passed the test. The process of taking samples from the batch for a test may be repeated twice :

Provided that if the same organism is visible in more than one test the batch shall be treated as not sterile and the material contained in the batch shall not be issued or used as part of a further batch unless and until it has been resterilized and has passed the tests.

120. Notwithstanding anything contained in the last preceding Rule in any case where—

- (a) a substance is required in an emergency by a registered medical practitioner, but the licensee has no filled containers in stock; or
- (b) a substance which in the opinion of the Licensing Authority is so unstable in solution that the delay occasioned by the completing of the sterility test on filled containers would render its issue in active form impossible, the licensee may issue the substance from a batch which has already passed the tests for sterility and freedom from abnormal toxicity, without completing the sterility test on the filled containers, provided that he complies with the following conditions—
 - (i) the licensee shall before the issue take samples in the required proportions from the containers into which the batch is filled, and after the required inoculation and incubation shall examine the tube every day for five days;
 - (ii) if at any examination any growth is visible in any of the tubes, he shall immediately notify the Licensing Authority;
 - (iii) he shall keep available for inspection a record of all issues made under this Rule containing such particulars of the circumstances in which the issue is made as the Licensing Authority may require.

121. *Test for freedom from abnormal toxicity*—The following tests for freedom from abnormal toxicity shall, in the case of each batch of serum, be made by the licensee or by some institution approved by the Licensing Authority for the purpose of carrying out the tests on his behalf—

- (a) A dose of 0.5 c.c. of serum shall be injected subcutaneously into a normal mouse and the serum may be treated as having passed the test for freedom from an excess of phenolic antiseptic if the injection does not produce death or serious symptoms within seven days; and
- (b) a dose of not less than 5 c.c. of the serum shall be injected subcutaneously or intraperitoneally into a normal guineapig and the serum shall be treated as having passed the tests for freedom from other abnormal toxic constituents if the injection does not produce death or serious symptoms within seven days.

*121-A. *Test for pyrogens*—Solution of substances intended for parenteral administration in large volumes (10 ml. or more at a time) shall

*Added under Government of India Notification No. F. 1-27/56-D, dated 18-12-1956.

be pyrogen-free and tested for pyrogens. If water or any other aqueous solvent is supplied along with the substances for preparing such solutions, it shall also be pyrogen-free and tested for pyrogens.

122. *Substances specified in Schedule C(1)*—The following provisions shall apply in the case of a substance specified in Schedule C(1) :—

@(a) The container shall comply with the requirements, if any, specified in Schedule F or Schedule F(1), as the case may be.

@ @ (b)

@(c) The substance shall conform to the standards of strength, quality and purity specified in Schedule F or Schedule F(1), as the case may be and the tests for determining the strength, quality and purity of the substance shall be those specified in Schedule F or Schedule F(1), as the case may be.

@(d) The tests for determining the strength, quality and purity of a substance specified in Schedule F or Schedule F(1) as the case may be shall be applied to samples taken from the final product after each manufacturing process has been completed.

(e) The substance should be stored in a cool place and away from light.

PART XI—EXEMPTIONS

123. The drugs specified in Schedule K shall be exempted from the provisions of Chapter IV of the Act and the Rules made thereunder to the extent and subject to the conditions specified in that Schedule.

PART XI—EXEMPTIONS

@ @ 124—*Standards of drugs* :—

(1) Drugs included in the Indian Pharmacopoeia.—

(a) The standards for identity, purity and strength shall be those as may be specified in the edition of the Indian Pharmacopoeia for the time being in force.

(b) In case the standards for identity, purity and strength for drugs are not specified in the edition of the Indian Pharmacopoeia for the time being in force but are specified in the edition of the Indian Pharmacopoeia immediately preceding, the standards for identity, purity and strength shall be those occurring in such immediately preceding edition of the Indian Pharmacopoeia.

(2) For other drugs,—

(a) The standards for identity, purity and strength shall be those as may be specified in the edition of the official pharmacopoeia, for the time being in force, of any country to which the drug claims to comply with.

(b) In case the standards for identify, purity and strength for drugs are not specified in the edition of such official pharmacopoeia,

@Amended by Govt. of India, Ministry of Health, F.P., W.H. and U.D. Notification No. F. 1-6/62-D, dated 2-7-1969.

@ @ Deleted or amended under G.S.R. No. 19 dated 7/1/78 (Govt. of India Notification No. X-11013/1/77-D & MS, dated 15/12/77).

for the time being in force, but are specified in the edition immediately preceding, the standards for identity, purity and strength shall be those occurring in such immediately preceding edition of such official pharmacopoeia to which the drug claims to comply with.

- (c) For drugs for which standards are not included in the edition of the official pharmacopoeia, for the time being in force, of any country or in edition immediately preceding, but included in the official compendia of drug standards, namely, the British Pharmaceutical Codex or the National Formulary of the United States, for the time being in force, to which the drug claims to comply with.

*124A. *Standards for Veterinary drugs.*—For drugs intended for veterinary use, the standards shall be those given in the current edition for the time being in force of the British Veterinary Codex.

***124-B. *Standards for patent or proprietary medicines* :—The standards for patent or proprietary medicines shall be those laid down in Schedule V and such medicines shall also comply with the standards laid down in the Second Schedule to the Act;

**125. *Standards for substances (other than food) intended to affect the structure or any function of human body—contraceptives.*—(1) The standards for mechanical contraceptives shall be such as are laid down in Schedule R

(2) The standards which other contraceptives will have to comply with shall be in conformity with the formulae approved as safe and efficacious by the Central Government. Such formula shall be displayed on the label of every container of such contraceptive.

†126. *Standards for substances intended to be used for the destruction of vermin or insects which cause disease in human beings or animals. Disinfectants.*

The standards for disinfectants shall be such as are laid down in Schedule O.

‡126-A *Standards for ophthalmic preparations*—The standards for ophthalmic preparations shall be those laid down in Schedule FF., and such preparations shall also comply with the standards set out in the Second Schedule to the Act.

@127. *List of colours permitted to be used in drugs.*—(1) No drug shall contain a colour other than that specified below :—

(1) *Natural Colours*

Annatto

Carotene

*Amended by Govt. of India, Ministry of Health, F. P., W. H. and U.D. Notification No. F. 1-6/62-D, dated 2-7-1969.

**Amended by Government of India, Ministry of Health and Family Planning Notification No. F-1-28/65D dated 8th March, 1966.

***Added under G. S. R. No. 665 dated 28th May, 1977 (Govt. of India Notification No. X. 11014/2/77-D&MS, dated the 6th May 1977).

†Amended by Govt. of India Notification No. F. 1-20/60-D, dated 24th January, 1964.

‡Added under Govt. of India, Ministry of Health, F. P. W. H. and U.D. Notification No. 1-113/60-D, dated 23th December, 1969.

@Amended by S. O. No. 289 dated 3rd February, 1973 (Govt. of India Notification No. X. 11014/17/72-D, dated 20-12-1972).

- Chlorophyll
 Cochineal
 Curcumin
 Red Oxide of iron
 Yellow Oxide of iron
 *Titanium Dioxide
 (2) *Artificial Colours*
 Caramel
 (3) *Coal Tar Colours*

Common name of the colour	Colour Index Number	Chemical Name
1	2	3
GREEN		
Quinazarine Green S.S.	61565	1, 4-bis (p-Toluidino) anthra-quinone.
Alizarin Cyanine Green F.	61570	Disodium salt of 1, 4-bis (O-sulfo-p-toluidino) anthra-quinone.
*Fast Green F.C.F.	42053	Disodium salt of 4-{[4-(N-ethyl-p Sulfobenzylamino)-phenyl]-(4-hydroxy-2-sulfoniumphenyl)-methylene } [1-(N-ethyl-N-p-sulfobenzyl)] Δ 2 5-cyclohexadienimine].
*Green S	44090	Monosodium salt of 4, 4-bis (dimethylamino)-diphenylmethene-(2-naphthol-3, 6-disulphonic acid);
YELLOW		
Tartrazine	19140	Trisodium salt of 3-carboxy-5-hydroxy-1-p-sulfophenyl-4-p Sulfophenyl azopyrazole.
Sunset Yellow FCF	15985	Disodium salt of 1-p-sulfophenyl-azo-2-naphthol-6-sulfonic acid.
Quinoline Yellow SS	47000	2-(2-quinolyl)-1, 3-indandione.
RED		
Amaranth	16185	Trisodium salt of 1-(4-sulfo-1-naphthylazo) 2-naphthol 3, 6-disulfonic acid.
Erythrosine	45430	Disodium salt of 9-O-carboxyphenyl-6-hydroxy 2,4,5,7-tetrido-3-isoxanthone.
Eosin YS or Eosine G	45380	Disodium salt of 2, 4, 5, 7-Tetra-bromo-9-p-carboxyphenyl-6-hydroxy 3-isoxanthone.
Toney Red or Sudan III	26100	1-p-phenylazophenylazo-2-naphthol.
Ponceau 4 R	16255	Trisodium salt of 1-(4-sulpho-1-1-naphthylazo)-2 naphthol-6 : 8-disulphonic acid.
Carmoisine	14720	Disodium salt of 2-(4-sulpho-1-naphthylazo)-1 naphthol-4 sulphonic acid.
Fast Red E	16045	Disodium salt of 2-(4-sulpho-1-naphthylazo)-2-naphthol-6-sulphonic acid.

*Added by Ministry of Health, Notification No. X. 11013/3/76—D & M.S. dated 19 August, 1978.

1	2	3
BLUE		
Indigo Carmine	73015	Disodium salt of indigotin-5 : -5 Disulphonic Acid.
@Brilliant Blue FCF	42090	Disodium salt of 4-[[4-(N-ethyl-p-sulfobenzylamino)-phenyl]-(2-sulfoniumphenyl)-methylene]-1-(N-ethyl-N-p-sulfobenzyl)- Δ 2, 5-cyclohexadienimine'
ORANGE		
Orange G	16230	Disodium salt of 1-phenylazo-2-naphthol-6, 8-disulfonic acid.
BROWN		
Resorcin Brown	20170	Monosodium salt of 4-p-sulfo-phenylazo-2-(2, 4-xylyl)azo-1, 3 resorcinol.
BLACK		
Naphthol Blue Black	20470	Disodium salt of 8-amino-7-p-nitro-phenylazo-2-phenylazo-2-phenylazo-1-naphthol-3, 6-disulfonic acid.

(4) LAKES

The Aluminium or calcium salts (lakes)
of any of the water-soluble colours listed above.

(2) The label on the container of a drug containing a permitted colour shall indicate the common name of the colour.

128. The following rules are hereby repealed except as respect things done or omitted to be done under those rules, namely :—

Andhra Pradesh Drugs Rules, 1945.

Assam Drugs Rules, 1945.

Bihar Drugs Rules, 1945.

Bombay Drugs Rules, 1946.

East Punjab Drugs Rules, 1945.

C.P. & Berar Drugs Rules, 1945.

Madras Drugs Rules, 1945.

Orissa Drugs Rules, 1945.

Rajasthan Drugs Rules, 1953.

Saurashtra Drugs Rules, 1953.

Travancore-Cochin Drugs Rules, 1953.

United Provinces Drugs Rules, 1945.

West Bengal Drugs Rules, 1946.

*Mysore Drugs Rules, 1954.

@Amended by Min. of Health Notification No. X. 11013/3-76-D & MS dated 19-8-78

*Added under Government of India Notification No. F. 1-37/58-D., dated 21st July 1958.

†PART XIII—IMPORT OF COSMETICS

129. *Statement to accompany imported cosmetics*—All consignments of cosmetics sought to be imported shall be accompanied by an invoice or statement showing the name and quantities of each article of cosmetic included in the consignment and the name and address of the manufacturer.

130. *Documents to be supplied to the Collector of Customs*—Before any cosmetics are imported, a declaration signed by or on behalf of the manufacturer or by or on behalf of the importer that the cosmetics comply with the provisions of Chapter III of the Act, and the Rules made thereunder, shall be supplied to the Collector of Customs.

131. *Procedure for the import of cosmetics*—(1) If the officer appointed at the port of entry by the Central Government has reason to believe that any cosmetic contravenes any of the provisions of the Act or the Rules made thereunder he may take sample of the cosmetic from the consignment for inspection. If on examination of the sample defects are noticed the officer shall advise the Collector of Customs for further action to be taken.

If the suspected contravention of the provisions of the Act or the Rules is such as may have to be determined by test, the officer shall send the sample to the laboratory established for the purpose for performing such tests. The consignment of the said cosmetic shall be detained till such time that the test report on such sample is received from the Director of the said laboratory or any other officer of the laboratory empowered by him in this behalf with the approval of the Central Government.

Provided that if the importer gives an undertaking in writing not to dispose of the cosmetic without the consent of the Collector of Customs and to return the consignment or such portion thereof as may be required, the Collector of Customs shall make over the consignment to the importer.

(2) If the importer who has given an undertaking under the proviso to sub-rule (1) is required by the Collector of Customs to return the consignment or portion thereof, he shall return the consignment or portion thereof within ten days of receipt of the notice.

Further procedure on receipt of the report of analysis.

(3) If the Director of the Laboratory established for the purpose by the Central Government or any other officer of the laboratory empowered by him in this behalf with the approval of the Central Government, reports to the Collector of Customs or to the officer mentioned in sub-rule (1) above that the sample of any cosmetic in a consignment contravenes the provisions of Chapter III of the Act or the Rules made thereunder and that the contravention is such that it cannot be remedied by the importer, the Collector of Customs shall communicate the report forthwith to the importer who shall within two months of receiving such a communication either send back all the cosmetic of that description to the country in which it was manufactured or to the country from which it was imported or hand it over to the Central Government which shall cause it to be destroyed.

Provided that the importer may within thirty days of receipt of the report make a representation against the report to the Collector of Customs who shall forward the representation with a fresh sample of the cosmetic to the

†Added under Government of India Notification No. F. 1-36/64-D, dated 17-8-1964.

Drugs Controller, India, who after obtaining, if necessary, the report of the Director of the Central Drugs Laboratory shall pass orders thereon which shall be final.

(4) If the Drugs Controller or any other officer empowered by him in this behalf with the approval of Central Government reports to the Collector of Customs after inspection of the sample of cosmetic and if necessary, after obtaining a test report thereon that the sample of the said cosmetic contravenes in any respect the provisions of Chapter III of the Act or the Rules made thereunder but that the contravention is such that it can be remedied by the importer, the Collector of Customs shall communicate the report forthwith to the importer and permit him to import the cosmetic on his giving an undertaking in writing not to dispose of the cosmetic without the permission of the officer authorised in this behalf by the Central Government.

132. *Exemption of cosmetics*—Cosmetics as may be specified in Schedule D shall be exempted from the provisions of Chapter III of the Act and the Rules made thereunder to the extent and subject to the conditions specified in that Schedule.

133. *Import through points of entry*—No cosmetic shall be imported into India except through the points of entry specified in rule 43 A.

134. *Cosmetic to contain prescribed Coal Tar Colour*—(1) No cosmetic shall be imported which contains a Coal Tar Colour other than the one prescribed in Schedule Q to these rules.

The Coal Tar Colour used in the cosmetic shall not contain more than—

- (i) 2 parts per million of arsenic calculated as arsenic trioxide.
- (ii) 20 parts per million of lead calculated as lead.
- (iii) 100 parts per million of heavy metals other than lead calculated as the total of the respective metals.

(2) No cosmetic intended for use on the eye-brow, or the eyelash, or around the eye shall be imported that contains any Coal Tar Dye Colour, Coal Tar base or Coal Tar Dye intermediate.

*134-A. *Prohibition of import of cosmetic containing Hexachlorophene*—

No cosmetic containing hexachlorophene shall be imported.

135. *Import of cosmetic containing Lead or Arsenic compound prohibited*.—No cosmetic shall be imported in which a Lead or Arsenic compound has been used for purposes of colouring.

* Added by G.S.R. No. 116 dated 25-1-1975 (Govt. of India Notification No. X. 11013/3/74-D & MS dated the 15th January, 1975).

***135-A. *Import of cosmetics containing mercury compounds prohibited.* No cosmetic shall be imported which contains mercury compounds.

136. *Import of cosmetic for personal use*—Small quantities of cosmetics the import of which is otherwise prohibited under section 10 of the Act, may be imported for personal use subject to the following conditions :—

- (i) The cosmetics shall form part of a passenger's baggage and shall be the property of and be intended for, the bona fide use of the passenger; and
- (ii) The cosmetics shall be declared to the Customs authorities if they so direct.

PART XIV—MANUFACTURE OF COSMETIC FOR SALE

137. *Manufacture on more than one set of premises*—If cosmetics are manufactured on more than one premises, a separate application for each such premises shall be made and a separate licence obtained for each such premises.

138. *Application for licence to manufacture cosmetics*—**(1) Application for grant or renewal of licence to manufacture any cosmetic for sale shall be made to the Licensing Authority appointed by the State Government for the purpose of this Part (hereinafter in this Part referred to as the Licensing Authority) in Form 31 and shall be accompanied by a fee of rupees two hundred and an inspection fee of rupees fifty for the first inspection or rupees twenty-five in case of inspection for renewal of licence :

Provided that in case of small scale manufacturer employing not more than five persons, the application shall be accompanied by a fee of rupees forty and an inspection fee of rupees ten for the first inspection or rupees five in case of inspection for renewal of licence.

**(2) If a person applies for the renewal of licence after expiry but within six months of such expiry, the fee payable for the renewal of such licence shall be rupees two hundred plus an additional fee at the rate of rupees one hundred per month or a part thereof and an inspection fee of rupees twenty five :

Provided that in case of a small scale manufacturer employing not more than five persons, the fee payable for the renewal of such licence after its expiry but within six months of such expiry shall be rupees forty plus an additional fee at the rate of rupees twenty per month or a part thereof and inspection fee of rupees five.

(3) Application by a licensee to manufacture additional items of cosmetics shall be accompanied by a fee of rupees five for each item.

Provided that in the case of a small scale manufacturer employing not more than five persons the application to manufacture additional items shall be accompanied by a fee of rupee one for each item.

(4) A fee of rupees fifty and a fee of rupees ten shall be paid for a duplicate copy of a licence issued under sub-rule (1) and the proviso to sub-rule (1) respectively if the original is defaced, damaged or lost.

*Amended by G.R.S. No. 245 dated 21-2-1976 (Govt. of India Notification No. X. 13/5/72-D & MS, dated the 3rd February, 1976).

**Added by Min. of Health & F.W. Notification No. X. 11013/76-D & MS dated 8-1978.

****138-A Application for loan licence to manufacture cosmetics.**

- (1) Application for grant or renewal of a loan licence for the manufacture for sale of cosmetics shall be made in Form 31-A to the Licensing Authority and shall be accompanied by a fee of rupees one hundred.

*Explanation :—*For the purpose of this rule a 'loan licence' means a licence which a Licensing Authority may issue to an applicant who does not have his own arrangements for manufacture but who intends to avail himself of the manufacturing facilities owned by a licensee in Form 32.

- (2) If a person applies for the renewal of a loan licence after its expiry but within six months of such expiry, the fee payable for the renewal of such a licence shall be rupees one hundred plus an additional fee at the rate of rupees fifty per month or part thereof.
- (3) The Licensing Authority shall, before the grant of a loan licence, satisfy himself that the manufacturing unit has adequate equipments, staff, capacity for manufacture and facilities to undertake the manufacture on behalf of the applicant for a loan licence.
- (4) The loan licence shall be granted by the Licensing Authority to only such applicants who propose to avail of the facilities of manufacture of cosmetics in the premises of a manufacturer located in the same State where the applicant is located. In case the manufacture of cosmetic involves any special process of manufacture or use of equipments which are not available in the State where the applicant is located, the Licensing Authority after consulting the Licensing Authority where the manufacturing unit is located, may grant the loan licence.
- (5) Subject to the provisions of sub-rule (2), application for manufacture of additional items on a loan licence shall be accompanied by a fee of rupees five for each item.
- (6) A fee of rupees twenty-five shall be paid for a duplicate copy of a licence issued under sub-rule (1) if the original is defaced, damaged or lost;

139. *Conditions for the grant or renewal of a licence in Form 32—*
Before a licence in Form 32 is granted or renewed, the following conditions shall be complied with by the applicant :

(1) The manufacture shall be conducted under the direction and personal supervision of a competent technical staff consisting of at least one person who is a whole time employee and who possesses any one of the following qualifications :

- (a) holds a Diploma in Pharmacy approved by the Pharmacy Council of India under the Pharmacy Act, 1948 (8 of 1948),
or
- (b) is registered under the Pharmacy Act, 1948 (8 of 1948), or
- (c) has passed the Intermediate Examination with Chemistry as one of the subjects or an examination recognised by the Licensing Authority as equivalent to it.

Provided that in the case of small scale manufacturers employing not more than five persons, the following shall also be deemed to be the minimum qualification for a competent technical staff.

- (d) has had general training and practical experience extending over a period of not less than four years in the manufacture of cosmetics and which, in the opinion of the Licensing Authority, is adequate.

(2) The factory premises are situated in hygienic surroundings and are kept clean.

@(3) The premises where cosmetics are manufactured shall be distinct and separate from the premises used for residential purposes.

(4) The applicant shall provide adequate space, plant and equipment for the manufacturing process.

(5) The applicant shall either—

- (i) provide and maintain adequate staff, premises and laboratory equipment for testing the cosmetic manufactured, and the raw materials used in the manufacture, or
- (ii) make arrangements with some institution approved by the Licensing Authority under Part XV(A) of these rules for such tests to be regularly carried out in this behalf by the institution.

****139-A. Form of licence to manufacture cosmetics for sale.**—A licence to manufacture cosmetics for sale against application in Form 31, shall be granted in Form 32.

****139-B. Form of loan licence to manufacture cosmetics for sale.**—A loan licence to manufacture cosmetics for sale against application in Form 31-A shall be granted in Form 32-A.

140. Duration of licence.—An original licence or a renewed licence shall unless sooner suspended or cancelled be valid up to the 31st December, of the year following the year in which it is granted or renewed.

*Provided that if the application for renewal of a licence in force is made before its expiry or if the application is made within six months of its expiry, after payment of additional fee, the licence shall continue to be in force until orders are passed on the application and the licence shall be deemed to have expired, if application for its renewal is not made within six months of its expiry.

141. Certificate of renewal.—The certificate of renewal of a licence in Form 32 shall be issued in Form 33.

****141-A. Certificate of renewal of a loan licence.**—The certificate of renewal of a licence in Form 32-A shall be issued in Form 33-A.

****141-AA. Duration of a loan licence.**—An original loan licence in Form 32-A or a renewed loan licence in Form 33-A, unless sooner suspen-

@Added by the G.S.R. No. 245 dated 21-2-1976 (Govt. of India Notification No. X. 11013/5/72-D. & MS dated 3rd February, 1976).

*Amended by S.O. No. 2139 dated 21-8-1972 (Govt. of Notification No. X. 11014/12/72-D dated the 5th June, 1972).

**Added by G.S.R. No. 444, dated 28-4-1973 (Govt. of India Notification No. X. 11014/4/72-D dated the 31st March, 1973).

ded or cancelled, shall be valid upto the 31st December, of the year following the year in which it is granted or renewed;

Provided that if the application for the renewal of a licence is made before its expiry, or if the application is made within six months of its expiry, after payment of the additional fee, the licence shall continue to be in force until orders are passed on the application. The licence shall be deemed to have expired if the application for its renewal is not made within six months of its expiry.

142. *Conditions of licence.*—A licence in Form 32 shall be subject to the conditions stated therein and to the following other conditions, namely :—

- (a) the licensee shall provide and maintain staff, premises and equipment as specified in rule 139.
- (b) the licensee shall comply with the provisions of the Act and the Rules made thereunder and with such further requirements, if any, as may be specified in any rules to be made hereafter under Chapter IV of the Act.
- *** (b-1) the licensee shall keep records of the details of each batch of cosmetic manufactured by him and of raw materials used therein as per particulars specified in Schedule U(I) and such records shall be retained for a period of three years.
- (c) the licensee shall test each batch or lot of the raw materials used by him for the manufacture of the cosmetics and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests. The records or registers shall be retained for a period of three years from the date of manufacture.
- (d) the licensee shall allow any *Inspector appointed under the Act to enter with or without prior notice any premises where the manufacture of a substance in respect of which the licence is issued is carried on, to inspect the premises and to take samples of the manufactured products under a receipt.
- (e) the licensee shall allow an Inspector to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and the Rules made thereunder have been complied.
- @ (f) the licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impression and the defects noticed.

****142-A. Additional information to be furnished by an applicant for licence or a licensee to the Licensing Authority.**—The applicant for the grant of a licence or any person granted a licence under this Part shall, on demand, furnish to the Licensing Authority, before the grant of the licence or

***Added by G.S.R. 1594 dated 13-11-76 (Govt. of India Notification No. X. 11914/4/76-D & MS, dated 28-10-1976).

@Amended by Govt. of India Ministry of Health, F-P. & U.D. Notification No. F. 1-14/68-D, dated 26-10-1968).

**Added by S.O. No. 2139 dated 12-8-1932 (Govt. of India Notification No. X. 11014/12/72-D dated the 5th June, 1972).

*Added by G.S.R. No. 444 dated 28-4-1973 (Govt. of India Notification No. X. 10-14/4/72-D (Pt.) dated the 31st March, 1973).

during the period of licence is in force, as the case may be, documentary evidence in respect of the ownership or occupation on rental or other basis of the premises, specified in the application for licence or in the licence granted, constitution of the firm, or any other relevant matter, which may be required for the purpose of verifying the correctness of the statements made by the applicant or the licensee, while applying for or after obtaining the licence as the case may be.

***142-B. *Conditions of licence in Form 32-A*

- (a) A licence in Form 32-A shall be deemed to be cancelled or suspended, if the licence owned by the licensee, in Form 32, whose manufacturing facilities are cancelled or suspended, as the case may be under these Rules.
- (b) The licensee shall comply with the provisions of the Act and these rules and with such further requirements, if any, as may be specified from time to time in Chapter IV of the Act, provided that where such further requirements are specified in the rules, these would come into force four months after publication in the Official Gazette.

****(b-1) the licensee shall keep records of the details of each batch of cosmetic manufactured by him and of raw materials used therein as per particulars specified in Schedule U(I) and such records shall be retained for a period of three years.

- (c) The licensee shall test each batch or lot of the raw materials used by him for the manufacture of the cosmetics and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests. The records or registers shall be retained for a period of three years from the date of manufacture.
- (d) The licensee shall allow an Inspector appointed under the Act to enter with or without prior notice any premises where the manufacture of a substance in respect of which the licence is issued is carried on, to inspect the premises and to take samples of the manufactured products under a receipt.
- (e) The licensee shall allow an Inspector to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act, and the rules made thereunder have been complied.
- (f) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.

143. *Cancellation and suspension of licences.*—(1) The Licensing Authority may, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, cancel a licence issued under this Part or suspend it for such period as he thinks, fit, either wholly or in respect of some of the substances to which it relates, if in his opinion, the licensee has failed to comply with any of

**Added by G.S.R. No. 444 dated 28-4-1973 (Govt. of India Notification No. X. 014/4/72 D(Pt.) dated the 31st March, 1973).

***Added by G.S.R. 1594 dated 13-11-76 (Govt. of India Notification No. X. 11014/4/76-D & MS, dated 28-10-1976).

the conditions of the licence or with any provisions of the Act or the rules made thereunder.

(2) A licensee whose licence has been suspended or cancelled may appeal within a period of three months from the date of the order to the State Government which shall after considering the appeal, pass orders, and such orders shall be final.

144. *Prohibition of manufacture of cosmetics with Coal Tar Colours other than those prescribed.*—(1) No cosmetics shall be manufactured which contains a coal tar colour other than the one prescribed in Schedule Q to these Rules. The coal tar colour used in the manufacture of the cosmetic shall not contain more than :

- (i) 2 parts per million of arsenic calculated as arsenic trioxide.
- (ii) 20 parts per million of lead calculated as lead.
- (iii) 100 parts per million of heavy metals other than lead calculated as the total of the respective metals.

(2) No cosmetic intended for use on the eye-brow, or eye-lash or around the eye shall be manufactured that contains any Coal Tar dye, Coal Tar dye base or Coal Tar dye intermediate.

@@144A. *Prohibition of manufacture of cosmetic containing Hexachlorophene.*—No cosmetic containing Hexachlorophene shall be manufactured.

145. *Use of Lead and Arsenic compounds for the purpose of colouring cosmetics prohibited.*—The use of Lead and Arsenic compounds for the purpose of colouring cosmetics is prohibited.

**145-A. *Form of intimation for purpose of taking samples of cosmetics.*—Where an Inspector takes a sample of a cosmetic for the purpose of test or analysis, he shall intimate such purpose in writing in Form 17 to the person from whom he takes it.

145-B. *Form of receipt for seized cosmetics.*—A receipt by an Inspector for the stock of any cosmetic seized under clause (c) of sub-section (1) of section 22 of the Act, shall be in Form 16.

***145-C *Form of order not to dispose of stocks of cosmetics.*—An order in writing by an Inspector under clause (c) of sub-section (1) of section 22 of the Act requiring a person not to dispose of any stock of cosmetics in his possession shall be in Form 15.

†145-D. *Prohibition of manufacture of cosmetics containing mercury compounds.*—No cosmetic containing mercury compounds shall be manufactured.

*PART XV--LABELLING, PACKING AND STANDARDS OF COSMETICS

146. *Prohibition of sale or distribution.*—Subject to the other provisions of these rules, no person shall sell or distribute any cosmetic unless the

@@Added by G.S.R. No. 116 dated 25-1-1975 (Govt. of India Notification No. X-11013/3/74-D & MS dated the 15th January, 1975).

†Added by Min. of Health & F. W. Notification No. X. 11013/3/76-D & MS dated 19-8-1978.

*Amended by Govt. of India, Ministry of Health and F.P. Notification No. F. 1-15/66-D, dated 1-11-1966.

**Added by S. O. No. 2139- dated 12th August, 1972 (Govt. of India Notification No. X. 11014/12/72-D, dated the 5th June, 1972).

***Added by G. S. R. 1594 dated 13-11-76 (Govt. of India Notification No. X. 11014/4/76 D & MS, dated 28th October, 1976).

cosmetic, if of Indian origin, is manufactured by a licensed manufacturer and labelled and packed in accordance with these rules.

147. *Exemption of certain cosmetics from the provision of this part.*—Labels on packages or containers of cosmetics not manufactured for consumption or sale in India shall be adapted to meet the specific requirements, if any, of the law of the country to which the cosmetic is to be exported and shall give on the label—

- (a) the name of the cosmetic, and
- (b) the name of the manufacturer.

148. *Manner of labelling.*—Subject to other provisions of the rules, a cosmetic shall carry.

- (1) on both the inner and outer labels
 - (a) the name of the cosmetic,
 - (b) the name and the principal place of business of the manufacturer.
- (2) On the outer label—

A declaration of the net contents expressed in terms of weight for solids, fluid measure for liquids, weight for semi solids, combined with numerical count if the content is sub-divided :

Provided that this statement need not appear in case of a package of perfume, toilet water or the like the net content of which does not exceed 60 ml or any package of solid or semi-solid cosmetic the net content of which does not exceed 30 grams.

- (3) On the inner label, where a hazard exists—
 - (a) Adequate direction for safe use.
 - (b) Any warning, caution or special direction required to be observed by the consumer,
 - (c) A statement of the names and quantities of the ingredients that are hazardous or poisonous.

* (4) a distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figures representing the batch number being preceded by the letter "B", provided that this clause shall not apply to any cosmetic containing 10 grams or less if the cosmetic is in solid or semi-solid state, and 25 millilitres or less if the cosmetic is in a liquid state;

* (5) manufacturing licence number, the number being preceded by the letter 'M'.

(6) Where a package of a cosmetic has only one label such label shall contain all the information required to be shown on both the inner and the outer labels, under these Rules.

149. *Labelling of Hair dyes containing Coal Tar Colours.*—Hair dyes containing para-phenylene-diamine or other coal-tar dye base or coal-tar dye intermediate shall be labelled with the following legend in English and

*Amended or added by G.S.R. No. 245 dated 21-2-1976 (Govt. of India Notification No. X. 11013/5/72-D & MS dated the 3rd February, 1976).

local languages and these shall appear on both the inner and the outer labels.

“Caution.—This product contains ingredients which may cause skin irritation in certain cases and so a preliminary test according to the accompanying directions should first be made. This product should not be used for dyeing the eye-lashes or eye-brows; as such a use may cause blindness”.

Each package shall also contain instructions in English and local languages on the following lines for carrying out the test :

“This preparation may cause serious inflammation of the skin in some cases and so a preliminary test should always be carried out to determine whether or not special sensitivity exists. To make the test, cleanse a small area of skin behind the ear or upon the inner surface of the forearm, using either soap and water or alcohol. Apply a small quantity of the hair dye as prepared for use to the area and allow it to dry. After twenty four hours, wash the area gently with soap and water. If no irritation or inflammation is apparent, it may be assumed that no hypersensitivity to the dye exists. The test should, however, be carried out before each and every application. This preparation should on no account be used for dyeing eye-brows or eye-lashes as severe inflammation of the eye or even blindness may result”.

150. *Report of result of test or analysis of cosmetics.*—Test reports on samples of cosmetics taken for test or analysis under these Rules shall be supplied in Form 34.

*150-A

@PART XV (A)

APPROVAL OF INSTITUTIONS FOR CARRYING OUT TESTS ON DRUGS, COSMETICS AND RAW MATERIALS USED IN THEIR MANUFACTURE ON BEHALF OF LICENSEES FOR MANUFACTURE FOR SALE OF DRUGS/COSMETICS.

150-B. *Application for grant of approval for testing drugs/cosmetics—*

- (1) Application for grant or renewal of approval for carrying out tests for identity, purity, quality and strength on drugs or cosmetics or the raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of drugs or cosmetics, shall be made in Form 36 to the Licensing Authority appointed by the State Government for the purposes of Part VII, VII(A) or XIV of these Rules, as the case may be and referred to as the “approving authority” under this Part and shall be accompanied by an inspection fee of rupees five hundred in the case of testing of drugs specified in Schedules C and C(1) and rupees three hundred in the case of testing of drugs other than those specified in Schedule C and C(1), Homoeopathic drugs and cosmetics;

Provided that the applicant shall furnish to the approving authority such additional information as may be required by him in connection with the application in Form 36;

@Added under Govt. of India, Ministry of Health & F.W. Notification No. X. 11014/7/76/D & MS, dated 23-8-1977.

*Deleted under G.S.R. No. 1098, dated 24-7-1976 (Govt. of India Notification No. X. 11014/2/76-D & MS, dated 9-7-1979).

Provided further that if the applicant applied for renewal of approval after its expiry but within six months of such expiry, the inspection fee payable shall be rupees five hundred plus an additional inspection fee at the rate of rupees four hundred per month in the case of testing of drugs specified in Schedule C and C(1) and rupees three hundred plus an additional inspection fee of rupees two hundred per month in the case of testing of drugs other than those specified in Schedule C and C(1), Homoeopathic drugs and cosmetics;

- (2) A separate application shall be made for grant of approval for carrying out tests on additional categories of drugs or items of cosmetics.

Explanation.—For the purpose of this Part, the words ‘drugs’ and ‘cosmetics’ shall also mean and include the raw materials used in the manufacture of drugs including Homoeopathic drugs or cosmetics, as the case may be.

150-C. *Form in which approval to be granted for carrying out tests on drugs/cosmetics on behalf of licensees for manufacture of drugs/cosmetics and conditions for grant or renewal of such approval—*

- (1) Approval for carrying out such tests of identity, purity, quality and strength of drugs or cosmetics as may be required under the provisions of these rules, on behalf of licensee for manufacture of drugs or cosmetics shall be granted in Form 37.
- (2) Before approval in Form 37 is granted or renewed, the following conditions shall be complied with by the applicant :—
1. The premises where the tests are being carried out shall be well lighted and properly ventilated except where the nature of tests of any drug or cosmetic warrants otherwise. Wherever necessary, the premises shall be air conditioned so as to maintain the accuracy and functioning of laboratory instruments or to enable the performance of special tests such as sterility tests, microbiological tests etc.,
 2. The applicant shall provide adequate space having regard to the nature and number of samples of drugs or cosmetics proposed to be tested;

Provided that the approving authority shall determine from time to time whether the space provided continues to be adequate.

3. If it is intended to carry out tests requiring the use of animals, the applicant shall provide for an animal house and comply with the following requirements :—
 - (a) The animal house shall be adequate in area, well lighted and properly ventilated and the animals undergoing tests shall be kept in air conditioned area.
 - (b) The animals shall be suitably housed in hygienic surroundings and necessary provision made for removal of excreta and foul smell.
 - (c) The applicant shall provide for suitable arrangements for preparation of animal feed.

- (d) The applicant shall provide for suitable arrangements for quarantining of all animals immediately on their receipt in the institution.
 - (e) The animals shall be periodically examined for their physical fitness.
 - (f) The applicant shall provide for isolation of sick animals as well as animals under test.
 - (g) The applicant shall ensure compliance with the requirements of the Prevention of Cruelty to Animal Act, 1960 (59 of 1960).
 - (h) The applicant shall make proper arrangements for the disposal of the carcasses of animals in a manner as not to cause hazard to public health.
- (4) The applicant shall provide and maintain suitable equipment having regard to the nature and number of samples of drugs or cosmetics intended to be tested which shall be adequate in the opinion of the approving authority.
- (5) The testing of drugs or cosmetics, as the case may be, shall be under the active direction of a person whose qualifications and experience are considered adequate in the opinion of the approving authority and who shall be held responsible for the reports of test or analysis issued by the applicant.
- (6) The testing of drugs or cosmetics, as the case may be, for identity, purity, quality and strength shall be carried out by persons whose qualifications and experience of testing are adequate in the opinion of the approving authority.
- (7) The applicant shall provide books of standard recognised under the provisions of the Act and the Rules made thereunder and such books of reference as may be required in connection with the testing or analysis of the products for the testing of which approval is applied for.

150-D : Duration of approval : An approval granted in Form 37 or renewed in Form 38, unless sooner suspended or withdrawn, shall be valid up to the 31st December, of the year following the year in which it is granted or renewed.

Provided that if an application for the renewal of an approval in Form 37 is made before its expiry or if the application is made within six months of its expiry after the payment of the additional fee, the approval shall continue to be in force until orders are passed on the applications and the approval shall be deemed to have expired if the application for its renewal is not made within six months of its expiry.

150-E : Conditions of approval : An approval in Form 37 shall be subject to the following general conditions :—

- (a) The institution granted approval under this Part (hereinafter referred to as the approved institution) shall provide and maintain an adequate staff and adequate premises and equipment as specified in rule 150-C.
- (b) The approved institution shall provide proper facilities for storage so as to preserve the properties of the samples to be tested by it.

- (c) The approved institution shall maintain records of tests for identity, purity, quality and strength carried out on all samples of drugs or cosmetics and the results thereof together with the protocols of tests showing the readings and calculation in such form as to be available for inspection and such records shall be retained in the case of substances for which an expiry date is assigned for a period of two years from the expiry of such date and in the case of other substances for a period of six years.
- (d) The approved institution shall allow the Inspector appointed under this Act to enter with or without prior notice the premises where the testing is carried on and to inspect the premises and the equipment used for test and the testing procedures employed. The institution shall allow the Inspectors to inspect the registers and records maintained under these Rules and shall supply to such Inspectors such information as they may require for the purpose of ascertaining whether the provisions of the Act and Rules made thereunder have been observed.
- (e) The approved institution shall from time to time report to the approving authority any changes in the person-in-charge of testing of drugs or cosmetics or in the expert staff responsible for testing as the case may be and any material alterations in the premises or changes in the equipment used for the purposes of testing which have been made since the date of last inspection made on behalf of the approving authority before the grant or renewal of approval.
- (i) The approved institution shall furnish reports of the results of test or analysis in Form 39.
- (g) In case any sample of a drug or a cosmetic is found on test to be not of standard quality, the approved institution shall furnish the approving authority with copy of the test report on the sample with the protocols of tests applied.
- (h) The approved institution shall comply with the provisions of the Act and Rules made thereunder and with such further requirements, if any, as may be specified in the rules subsequently made under Chapter IV of the Act of which the approving authority has given the approved institution not less than four months notice.
- (i) The approved institution shall maintain an Inspection Book to enable the Inspectors to record his impressions or defects noticed.

150-F : Inspection before grant of approval : Before an approval in Form 37 is granted, the approving authority shall cause the institution at which the testing of drugs or cosmetics, as the case may be, is proposed to be carried out to be inspected jointly by the Drugs Inspectors of the Central Drugs Standard Control Organisation and the State Drugs Control Organisation who shall examine the premises and the equipment intended to be used for testing of drugs or cosmetics and inquire into the professional qualifications of the expert staff to be employed.

150-G : Report of Inspection : The Drug Inspectors mentioned in rule 150-F shall forward to the approving authority a detailed report of the result of the inspection.

150-H : Procedure of approving authority :

- (1) If the approving authority after such further enquiry, if any, as he may consider necessary, is satisfied that the requirements of the rules made under the Act have been complied with and that the conditions of the approval and the Rules made under the Act will be observed, he shall grant an approval in Form 37.
- (2) If the approving authority is not so satisfied, he shall reject the application and shall inform the applicant of the reasons for such rejection and of the conditions which must be satisfied before an approval could be granted.

150-I : Further application after rejection : If within a period of six months from the rejection of an application for approval, the applicant informs the approving authority that the conditions laid down have been satisfied and deposits inspection fee of rupees fifty, the approving authority may, if, after causing a further inspection to be made, satisfied that the conditions for grant of approval have been complied with, grant the approval in Form 37.

150-J : Renewal : On an application being made for renewal the approving authority may cause an inspection to be made and if satisfied that the conditions of the approval and the Rules made under the Act are and shall continue to be observed shall issue a certificate of renewal in Form 38.

150-K : Withdrawal and suspension of approvals :

- (1) The approving authority may, after giving the approved institution an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, withdraw an approval granted under this Part or suspend it for such period as he thinks fit either wholly or in respect of some of the categories of drugs or items of cosmetics to which it relates, if in his opinion the approved institution has failed to comply with any of the conditions of the approval or with any provision of the Act or the Rules made thereunder.
- (2) Any approved institution whose approval has been suspended or withdrawn may within three months of the date of the order, appeal to the State Government which shall dispose of the appeal in consultation with a panel of competent persons appointed by it in this behalf and notified in the Official Gazette.

****PART XVI—MANUFACTURE FOR SALE OF AYURVEDIC (INCLUDING SIDDHA) OR UNANI DRUGS.**

151. Manufacture on more than one set of premises.—If Ayurvedic (including Siddha) or Unani drugs are manufactured on more than one set of premises, a separate application shall be made and a separate licence shall be obtained in respect of each such set of premises.

152. Licensing Authorities.—For the purpose of this Part the State Government shall appoint such Licensing Authorities and for such areas as may be specified in this behalf by notification in the Official Gazette.

****Added under Govt. of India, Ministry of Health, F.P., W.H. and U.D. Notification No. 1-23/6 dated the 2-2-1970.**

153. *Application for licence to manufacture Ayurvedic (including Siddha) or Unani drugs.*—(i) An application for the grant or renewal of a licence to manufacture for sale any Ayurvedic (including Siddha) or Unani drugs shall be made in Form 24-D to the Licensing Authority along with a fee of rupees sixty.

Provided that in the case of renewal the applicant may apply for the renewal of the licence before its expiry or within one month of such expiry:

Provided further that the applicant may apply for renewal after the expiry of one month but within three months of such expiry in which case the fee payable for renewal of such licence shall be rupees sixty plus an additional fee of rupees thirty.

(ii) A fee of rupees fifteen shall be payable for a duplicate copy of a licence issued under this rule, if the original licence is defaced, damaged or lost.

*153-A. *Loan Licence.*—(i) An application for the grant of renewal of a loan licence to manufacture for sale of any Ayurvedic (including Siddha) or Unani drugs shall be made in Form 25-E to the Licensing Authority along with a fee of rupees thirty.

Explanation.—For the purpose of this rule, a loan licence means a licence which a Licensing Authority may issue to an applicant who does not have his own arrangements for manufacture but intends to avail himself of the manufacturing facilities owned by a licensee in Form 25-D :

Provided that in the case of renewal the applicant may apply for the renewal of the licence before its expiry or within one month of such expiry:

Provided further that the applicant may apply for renewal after the expiry of one month, but within three months of such expiry in which case the fee payable for renewal of such licence shall be rupees thirty plus an additional fee of rupees fifteen.

(ii) A fee of rupees seven and paise fifty shall be payable for a duplicate copy of a licence issued under this rule, if the original licence is defaced, damaged or lost.

154. *Form of licence to manufacture Ayurvedic (including Siddha) or Unani drugs :* (1) Subject to the conditions of rule 157 being fulfilled, a licence to manufacture for sale any Ayurvedic (including Siddha) or Unani drugs shall be issued in Form 25-D. The licence shall be issued within a period of three months from the date of receipt of the application.

(2) A licence under this rule shall be granted by the licensing authority after consulting such expert in Ayurvedic (including Siddha) or Unani Systems of medicine as the case may be, which the State Government may approve in this behalf.

*154-A. *Form of loan licence to manufacture for sale Ayurvedic (including Siddha) or Unani drugs :—*

A loan licence to manufacture for sale any Ayurvedic (including Siddha) or Unani drugs shall be issued in Form 25-E.

*Added under G.S.R. No. 376 (E), Gazette of India, Pt. II, Sec. 3 Sub-Sec. (i)—extra-ordinary dt. 20-7-78 (Govt. of India, Notification No. X. 11013/2/77-DMS & FA, dated the 20th July, 1978).

(2) A licence under this rule shall be granted by the Licensing Authority after consulting such expert in Ayurvedic (including Siddha) or Unani Systems of medicine, as the case may be, which the State Government may approve in this behalf.

(3) The Licensing Authority shall, before the grant of a loan licence, satisfy himself that the manufacturing unit has adequate equipment, staff, capacity for manufacture and facilities for testing, to undertake the manufacture on behalf of the applicant for a loan licence.

155. *Certificate of renewal*—The certificate of renewal of a licence in Form 25-D shall be issued in Form 26-D.

*155-A. *Certificate of renewal of a loan licence*.—The certificate of renewal of a loan licence in Form 25-E shall be issued in Form 26-E.

156. *Duration of licence*—An original licence in Form 25-D or a renewed licence in Form 26-D, unless sooner suspended or cancelled shall be valid up to the 31st December of the year following the year in which it is granted or renewed.

Provided that if the application for the renewal of a licence is made before its expiry or within one month of its expiry, or if the application is made within three months of its expiry after payment of the additional fee of rupees thirty, the licence shall continue to be in force until orders are passed on the application. The licence shall be deemed to have expired, if application for its renewal is not made within three months of its expiry.

*156-A. *Duration of loan licence*.—An original loan licence in Form 25-E or a renewed loan licence in Form 26-E, unless sooner suspended or cancelled, shall be valid up to the 31st December of the year following the year in which it is granted or renewed.

Provided that if the application for the renewal of a loan licence is made in accordance with rule 153-A, the loan licence shall continue to be in force until orders are passed on the application. The licence shall be deemed to have expired, if application for its renewal is not made within three months of its expiry.

157. *Conditions for the grant or renewal of a licence in Form 25-D*—Before a licence in Form 25-D is granted or renewed in Form 26-D the following conditions shall be complied with by the applicant, namely :—

(1) The manufacture of Ayurvedic (including Siddha) or Unani drug shall be carried out in such premises and under such hygienic conditions as are specified in Schedule T.

(2) The manufacture of Ayurvedic (including Siddha) or Unani drug shall be conducted under the direction and supervision of competent technical staff consisting at least of one person, who is a wholetime employee and who possesses the following qualifications, namely :—

(a) A degree in Ayurveda or Ayurvedic Pharmacy, Siddha or Unani system of medicine, as the case may be, conferred by a University, a State Government or Statutory Faculties, Councils and Boards of Indian Systems of Medicine.

*Added under G.S.R. No. 376(E), Gazette of India, Pt. II, Sec. 3, Sub-Sec. (i), Extraordinary dated 20th July, 1978. (Govt. of India Notification No. X 11013/2/77 DMS & PFA dated the 20th July, 1978).

of medicine recognised by the Central Government or a State Government for this purpose, or

(b) a diploma in Ayurveda, Siddha or Unani system of medicine granted by a State Government or an Institution recognised by the Central Government for this purpose, or

(c) a graduate in Pharmacy or Pharmaceutical Chemistry or Chemistry or Botany of a University recognised by the Central Government with experience of at least two years in the manufacture of drugs pertaining to the Ayurvedic or Siddha or Unani systems of medicine, or

(d) a Vaid or Hakim registered in a State Register of Practitioners of indigenous systems of medicines having experience of at least four years in the manufacture of Ayurvedic or Siddha or Unani drugs, or

(e) a qualification as Pharmacist in Ayurvedic (including Siddha) or Unani systems of medicine, possessing experience of not less than eight years in the manufacture of Ayurvedic or Siddha or Unani drugs as may be recognised by the Central Government.

(3). The competent technical staff to direct and supervise the manufacture of Ayurvedic drugs shall have qualifications in Ayurveda and the competent technical staff to direct and supervise the manufacture of Siddha drugs and Unani drugs shall have qualification in Siddha or Unani, as the case may be.

158. *Conditions of licence*—A licence in Form 25-D shall be subject to the conditions stated therein and to the following further conditions, namely :—

(a) The licensee shall maintain proper records of the details of manufacture and of the tests, if any, carried out by him, or by any other person on his behalf, of the raw materials and finished products.

(b) The licensee shall allow an Inspector appointed under the Act to enter any premises where the manufacture of a substance in respect of which the licence is issued is carried on, to inspect the premises, to take samples of the raw material as well as the finished products, and to inspect the records maintained under these rules.

*158-A. *Condition of loan licence*.—A licence in Form 25-E shall be subject to the conditions stated therein and to the following conditions, namely :—

(a) The licence in Form 25-E shall be deemed to be cancelled or suspended, if the licence owned by the licensee in Form 25-D whose manufacturing facilities have been availed of by the licensee is cancelled or suspended, as the case may be, under these rules.

(b) The licensee shall comply with the provisions of the Act and of the Rules and with such further requirements if any, as may be specified in any Rules subsequently made under Chapter IV-A of the Act, provided that where such further requirements are specified in the Rules; these would come into force four months after publication in the Official Gazette.

(c) The licensee shall maintain proper records of the details of manufacture and of the tests, if any, carried out by him, or

*Added under G.S.R. No. 376 (F), Gazette of India, Pt. II, Sec. 3, Sub-Sec.(1)—Extraordinary, dated 20-7-1978 (Govt. of India Notification No. X. 11013/2/77-DMS&PFA, dated the 20th July, 1978).

any other person on his behalf, of the raw materials and finished products.

- (d) The licensee shall allow an Inspector appointed under the Act to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and the Rules have been observed.

159. *Cancellation and suspension of licences*—(1) The Licensing Authority may, after giving the licensee an opportunity to show cause, within a period which shall not be less than fifteen days from the date of receipt of such notice, why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under this Part or suspend it for such period as he thinks fit, either wholly or in respect of some of the drugs to which it relates, if in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act and the Rules made thereunder.

(2) A licensee whose licence has been suspended or cancelled may appeal to the State Government within a period of three months from the date of receipt of the order which shall, after considering the appeal, decide the same.

160. *Identification of raw materials*—Raw materials used in the preparation of Ayurvedic (including Siddha) or Unani drugs shall be identified and tested, wherever tests are available for their genuineness, and records of such tests as are carried out for the purpose and the methods thereof shall be maintained.

PART XVII—LABELLING AND PACKING OF AYURVEDIC (INCLUDING SIDDHA) OR UNANI DRUGS

161. *Manner of labelling*—(1) There shall be conspicuously displayed on the label of the container or package of an Ayurvedic (including Siddha) or Unani drug, the true list of all the ingredients used in the manufacture of the preparation together with the quantity of each of the ingredients incorporated therein and a reference to the method of preparation thereof as detailed in the standard text and Adikarana, as are prescribed in the authoritative books specified in the First Schedule to the Act :

Provided that if the list of ingredients contained in the medicine is large and cannot be accommodated on the label, the same may be printed separately and enclosed with the packing and reference be made to this effect on the label.

(2) The container of a medicine for internal use made up ready for the treatment of human ailments shall, if it is made up from a substance specified in Schedule E(1), be labelled conspicuously with the words 'Caution : To be taken under medical supervision' both in English and Hindi language.

(3) Subject to the other provisions of these rules, the following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any

Ayurvedic (including Siddha) or Unani drug and on any other covering in which the container is packed namely :—

- (i) The name of the drug. For this purpose the name shall be the same as mentioned in the authoritative books included in the First Schedule of the Act.
 - (ii) A correct statement of the net content in terms of weight, measure or number as the case may be. The weight and volume shall be expressed in metric system.
 - (iii) The name and address of the manufacturer.
 - (iv) The number of the licence under which the drug is manufactured, the figure representing the manufacturing licence number being preceded by the words 'Manufacturing Licence Number' or 'Mfg. Lic. No.' or "M.L."
 - (v) A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figure representing the batch number being preceded by the words "Batch No." or "Batch" or "Lot Number" or "Lot No." or "Lot" or any distinguishing prefix.
 - (vi) The date of manufacture. For this purpose the date of manufacture shall be the date of completion of the final products, or the date of bottling or packing for issue.
 - (vii) The words "Ayurvedic medicine" or "Siddha medicine" or "Unani medicine" as the case may be.
 - (viii) The words "FOR EXTERNAL USE ONLY" if the medicine is for external application.
 - (ix) Every drug intended for distribution to the medical profession as a free sample shall, while complying with the labelling provisions under clauses (i) to (viii), further bear on the label of the container the words "Physicians sample. Not to be sold" which shall be over-printed.
- (4) Nothing in these rules shall be deemed to require the labelling of any transparent cover or of any wrapper-case or other covering used solely for the purpose of packing, transport or delivery.

PART XVIII—GOVERNMENT ANALYSTS AND INSPECTORS FOR AYURVEDIC (INCLUDING SIDDHA) OR UNANI DRUGS

162. *Duties of Inspectors specially authorised to inspect the manufacture of Ayurvedic (including Siddha) or Unani drugs*—Subject to the instructions of the controlling authority, it shall be the duty of an Inspector authorised to inspect the manufacture of Ayurvedic (including Siddha) or Unani drugs :—

- (i) to inspect not less than twice a year, all premises licensed for the manufacture of Ayurvedic (including Siddha) or Unani drugs within the area allotted to him and to satisfy himself that the conditions of the licence and the provisions of the Act and the Rules made thereunder are being observed;

(ii) to send forthwith to the Controlling Authority after each inspection a detailed report indicating whether or not the conditions of the licence and the provisions of the Act and the Rules made thereunder are being observed;

(iii) to take samples of the drugs manufactured on the premises and send them for test or analysis in accordance with these Rules;

(iv) to institute prosecutions in respect of violation of the Act and the Rules made thereunder.

163. *Procedure for despatch of sample to Government Analyst and its receipt by the Government Analyst*—(1) Sample for test or analysis shall be sent to the Government Analyst by registered post or by hand in a sealed package, enclosed together with a memorandum in Form 18-A in an outer cover addressed to the Government Analyst.

(2) The package as well as the outer cover shall be marked with a distinguishing number.

(3) A copy of the memorandum and a specimen impression of the seal used to seal the package shall be sent by registered post or by hand to the Government Analyst.

(4) On receipt of the package from an Inspector, the Government Analyst or an Officer authorised by him in writing in this behalf shall open the package and shall also record the conditions of the seals on the package.

(5) After the test or analysis has been completed, one copy of the results of the test or analysis shall be supplied forthwith to the sender in Form 13-A. A copy of the result in Form 13-A shall also be sent simultaneously to the Controlling Authority and to the Drugs Controller, India

164. *Method of test or analysis to be employed in relation to Ayurvedic (including Siddha) or Unani drugs*.—The method of test or analysis to be employed in relation to an Ayurvedic (including Siddha) or Unani drug shall be such as may be specified in the Ayurvedic (including Siddha) or Unani Pharmacopoeia, or if no such pharmacopoeias are available or if no tests are specified in such pharmacopoeias, such tests as the Government Analyst may employ, such tests being scientifically established to determine whether the drug contains the ingredients as stated on the label.

165. *Qualifications of Government Analyst*.—A person who is appointed a Government Analyst under section 33 F of the Act shall be a person possessing the qualifications prescribed in rule 44 or a degree in Ayurveda, Siddha or Unani System, as the case may be, conferred by a University, a State Government or Statutory Faculties, Councils and Boards of Indian Systems of Medicine recognised by the Central or State Government, as the case may be, for this purpose and has had not less than three years' post-graduate experience in the analysis of drugs in a laboratory under the control of (i) a Government Analyst appointed under the Act, or (ii) a Chemical Examiner to Government, or (iii) the Head of an institution specially approved for the purpose by the appointing authority.

166. *Duties of Government Analyst*—(1) The Government Analyst shall analyse or test or cause to be analysed or tested such samples of Ayurvedic (including Siddha) or Unani drugs as may be sent to him by Inspectors or any other persons or authority authorised by the Central Government or a State Government under the provisions of Chapter IVA of the Act and shall furnish reports of the results of test or analysis in accordance with these rules.

(2) A Government Analyst appointed under Section 33F shall from time to time forward to the Government reports giving the result of analytical work and research with a view to their publication at the discretion of the Government.

*167. *Qualifications of Inspector*.—A person who is appointed an Inspector under section 33 G shall be a person who—

- (a) has the qualifications laid down under rule 49 and shall have undergone practical training in the manufacture of Ayurvedic (including Siddha) or Unani drug, as the case may be; or
- (b) has a degree in Ayurvedic or Siddha or Unani System or a degree in Ayurveda Pharmacy, as the case may be, conferred by a University or a State Government or a Statutory Faculty, Council or Board of Indian Systems of Medicine recognised by the Central Government or the State Government for this purpose; or
- (c) has a diploma in Ayurveda, Siddha or Unani Systems, as the case may be, granted by a State Government or an Institution recognised by the Central Government or a State Government for this purpose.

SCHEDULE A

Form 1

[See Rule 4]

Memorandum to the Central Drugs Laboratory

Serial Number

To the Director, Central Drugs Laboratory

From

I send herewith, under the provisions of Section 25(4) of the Drugs and Cosmetics Act, 1940, sample(s) of a drug purporting to be for test or analysis and request that a report of the result of the test or analysis may be supplied to this Court.

2. The distinguishing number on the packet is

3. Particulars of offence alleged

*Amended under G. S. R. No 376 (E) Gazette of India, Pt. II, Sec. 3 Sub-Section (i) Extraordinary, dt.20-7-78 (Govt. of India Notification No. X. 11013/2/77-DM & PFA, dated the 20th July, 1978)

4. Matter on which opinion is required.....

5. A fee of Rs. has been deposited in Court.

Date

Magistrate

Form 2

[See Rule 6]

Certificate of test or analysis by the Central Drugs Laboratory

Certified that the sample, bearing number
purporting to be a sample of received on
with memorandum No. dated
from has been tested/analysed and that the result
of such test/analysis is as stated below.

2. The condition of the seals on the packet on receipt was as follows :—

*3. In the opinion of the undersigned the sample is of standard
quality as defined in the Drugs and Cosmetics Act, 1940, and Rules
quality as defined in the Drugs and Cosmetics Act, 1940, and Rules
thereunder is not of standard
thereunder for the reasons given below :—

Date

Director

Central Drugs Laboratory or other authorised Officer
Details of results of test or analysis with protocols of test applied

Date

Director

Central Drugs Laboratory or other authorised Officer

*If opinion is required on any other matter, the paragraph should be suitably amended

†Forms 3 to 7

Form 8

[See Rule 24]

*Application for licence to import biological and other special products
specified in Schedules C and C(1) to the Drugs and Cosmetics
Rules, 1945*

†Omitted under Government of India Notification No. F. 1-16/57-D, dated 15-6-1957.

I/We.....hereby apply for a licence to import drugs specified below manufactured by of

Names of drugs and classes of drugs

I/We enclose herewith an undertaking signed by or on behalf of the manufacturers as required by the Drugs and Cosmetics Rules, 1945.

A fee of rupees fifty has been credited to Government under the head of Account "080—Medical—Miscellaneous—fees under the Drugs and Cosmetics Rules, 1945—Central" vide treasury receipt attached.

Date

Manufacturer's Agent

FORM 9

[See Rule 24]

Form of undertaking to accompany an application for an import licence

Whereas of intends to apply for a licence under the Drugs and Cosmetics Rules, 1945, for the import into India, of the drugs specified below manufactured by us, we of hereby give this undertaking that for the duration of the said licence—

- (1) the said applicant shall be our agent for the import of drugs into India;
- (2) we shall comply with the conditions imposed on a licence by clause (a) to (e) of rule 78 of the Drugs and Cosmetics Rules, 1945;
- (3) we declare that we are carrying on the manufacture of the drugs mentioned in this undertaking at the premises specified below, and we shall from time to time report any change of premises on which manufacture will be carried on and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories;
- (4) we shall comply with the provisions of Part IX of the Drugs and Cosmetics Rules, 1945;
- (5) every drug manufactured by us for import under licence into India shall as regards strength, quality and purity conform with the provisions of Chapter III of the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetic Rules, 1945;
- (6) we shall comply with such further requirements, if any, as may be specified by Rules, by the Central Government under

the Act and of which the licensing authority has given to the licensee not less than four months' notice.

Names of drugs and classes of drugs

Particulars of premises where manufacture is carried on.

Date

Signed by or on behalf of the manufacturer

FORM 10

[See Rule 27]

Licence to import biological and other special products specified in Schedules C and C(1) to the Drugs and Cosmetics Rules, 1945

Number of licence
 of is/are hereby licensed to import into India during the period for which this licence is in force the drugs specified below manufactured by of

and any other drugs manufactured by
 as may from time to time be endorsed on this licence.

*(2) This is subject to the conditions prescribed in Drugs and Cosmetics Rules, 1945, and shall be in force from to unless it is sooner suspended or cancelled under the said Rules.

Names of drugs and classes of drugs to which the licence applies

(3) The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

Date

Licensing Authority

*Amended by Government of India Notification No. F. 1-10/62-D, dated 10th April, 1964.

FORM 11

[See Rule 33]

Licence to import drugs for the purposes of examination, test or analysis

..... of is hereby licensed to import from the drugs specified below for the purposes of examination, test or analysis at or in such other places as the licensing authority may from time to time authorize.

2. This licence is subject to the conditions prescribed in the Rules under the Drugs and Cosmetics Act, 1940.

3. This licence shall, unless previously suspended or revoked, be in force for a period of one year from the date specified below :—

Names of drugs

Quantities which may be imported

Date

Licensing Authority

FORM 12

[See Rule 34]

Application for licence to import drugs for purpose of examination, test or analysis

I resident of by occupation hereby apply for a licence to import the drugs specified below for the purposes of examination, test or analysis at from and I undertake to comply with the conditions applicable to the licence.

*A fee of rupees fifteen has been credited to Government under the head of Account '080'-Medical-Miscellaneous-fee under the Drugs and Cosmetics Rules, 1945—Central *vide* treasury receipt attached.

Names of drugs and classes of drugs

Quantities

Date

Signature

***FORM 12-A**

[See Rule 36, second proviso]

Application for the issue of a permit to import small quantities of drugs for personal use

I resident of by occupation hereby apply for a permit to import the drugs specified below for personal use from

I attach a prescription from a registered medical practitioner in regard to the need for the said drugs.

Names of drugs

Quantities

Date

Signature

*Added under Government of India Notification No. F. 1-36/54-DS, dated 3-3-1955.

*Added by S.O. No. 903 dated 28-2-1976 (Govt. of India Notification No. X. 11013/2/75-D&MS dated the 10th February, 1976).

FORM 12-B

[See Rule 36, second proviso]

Permit for the import of small quantities of drugs for personal use
 of is hereby permitted to
 import from the drugs specified below for personal
 use.

2. This permit is subject to the conditions prescribed in the Rules under the Drugs and Cosmetics Act, 1940.

3. This permit shall, unless previously suspended or revoked, be in force for a period of six months from the date specified below.

Names of drugs

Quantities which may be imported.

Date

Licensing Authority

FORM 13

[See Rule 46]

*Certificate of test or analysis by Government Analyst under Section 25(1)
 of the Drugs and Cosmetics Act, 1940*

1. Name of Inspector from whom received
2. Serial No. and date of Inspector's memorandum
3. Number of sample
4. Date of receipt
5. Names of drugs purporting to be contained in the sample.....
6. Condition of seals on the package
7. Result of test or analysis with protocols of test or analysis applied

In the opinion of the undersigned the sample referred to above is of
standard quality as defined in the Drugs and Cosmetics Act, 1940.
standard quality as defined in the Drugs and Cosmetics Act, 1940.
and Rules thereunder is not of
and Rules thereunder for the reasons given below :—

Date

Government Analyst.....

**FORM 13-A

[See Rule 163(5)]

*Certificate of tests or analysis by Government Analyst under Section
 33H of the Drugs and Cosmetics Act, 1940*

1. Name of Inspector from whom received
2. Serial No. and date of Inspector's memorandum

**Added under Govt. of India, Min. of Health, F.P., W.H. and U.D. Notification No. F 1-23/67-D, dated 2-2-1970.

3. Number of sample
4. Date of receipt
5. Names of ingredients purporting to have been used in the preparation of the sample
6. Condition of seals on the package
7. Results of test or analysis

Date

Government Analyst

FORM 14-A

[See Rule 47]

*Application from a purchaser for test or analysis of a drug under
Section 26 of the Drugs and Cosmetics Act, 1940*

1. Full name and address of the applicant
2. Occupation
3. Name of drug purporting to be contained in the sample
4. Name and full address of the pharmacy or concern where the drug was purchased.
5. Date on which purchased
6. Reasons why the drug is being submitted for test or analysis
.....

*7. A fee of rupees vide Schedule B to the Drugs and Cosmetics Rules, 1945, has been credited to Government under the head of account "O80—Medical—Miscellaneous—Fees under the Drugs and Cosmetics Rules, 1945—Central/State"—vide treasury receipt attached.

I hereby declare that the drug being submitted for test was purchased by or for me. I further declare that the sample of the drug being sent for test or analysis is exactly as it was purchased and has not been tampered with in any way to reduce its potency.

Date

Signed

FORM 14-B

[See Rule 47]

*Certificate of test or analysis by Government Analyst under Section
26 of the Drugs and Cosmetics Act, 1940*

1. Name of person from whom sample received
2. Date of receipt
3. Name of drug purporting to be contained in the sample

*Added under Government of India Notification No. F. 1-3/51 D.S, dated 15-10-1954.

4. *Opinion of the Government Analyst*—The sample referred to above is/is not of standard quality as defined in the Drugs and Cosmetics Act, 1940, and Rules thereunder.

Date.....

Government Analyst

****FORM 15**

[See Rules 54 and 145 C]

Order under Section 22 (1)(c) of the Drugs and Cosmetics Act, 1940, requiring a person not to dispose of stock in his possession

Whereas, I have reason to believe that the stocks of drugs/cosmetics in your possession, detailed below contravene the provisions of section 18 of the Drugs and Cosmetics Act, 1940;

Now, therefore, I hereby require you under clause (c) of sub-section (1) of section 22 of the said Act, not to dispose of the said stock for a period of.....days from the date of this order.

Date.....

Inspector.....

Details of stock of drugs/cosmetics

Date.....

Inspector.....

@FORM 16

[See Rules 55 and 145-B]

Receipt for stock of drugs or cosmetics or for record, register document or material object seized under section 22(1)(c) or (cc) of the Drugs and Cosmetics Act, 1940.

The stock of drugs or cosmetics or records, registers, documents or material objects detailed below has/have this day been seized by me under the provisions of clause (c) or clause (cc) of sub-section (1) of section 22 of the Drugs and Cosmetics Act, 1940 (23 of 1940) from the premises of.....situated at.....

Date.....

Inspector.....

Details of drugs, cosmetics, records, registers, documents or material objects seized.

Date.....

Inspector.....

@Amended by G.S.R. No. 926 dated 16-7-1977 (Government of India Notification No. X. 11014/6/76-D&MS, dated 24-6-1977).

**Amended by G.S.R. No. 1594, dated 12-11-1976 Government of India Notification No. X. 11014/4/76-D&MS, dated 28-10-1976.

*FORM 17

[See Rules 56 and 145-A]

Intimation to person from whom sample is taken

To.....

I have this day taken from the premises of situated at..... samples of the drugs/cosmetics specified below for the purpose of test or analysis.

Date.....

Inspector.....

Details of samples taken

Date.....

Inspector.....

FORM 18

[See Rule 57]

Memorandum to Government Analyst

Serial No. of Memorandum.....
From

To

The Government Analyst.

The portion of sample/container described below is sent herewith for test or analysis under the provisions of clause (i) of sub-section (4) of Section 23 of the Drugs and Cosmetics Act, 1940.

The portion of sample/container has been marked by me with the following mark.

Details of portion of sample or container with name of drug which it purports to contain—

Date.....

Inspector.....

†FORM 18-A

[See Rule 163(1)]

Memorandum to Government Analyst

Serial No.

From

To

The Government Analyst.

The portion of sample/container described below is sent herewith for test or analysis under the provisions of Section 33H of the Drugs and Cosmetics Act, 1940.

†Added under Govt. of India, Min. of Health, F.P., W.H. & U.D. Notification No. F. 1-23/67-D, dated 2-2-1970.

*Amended by S.O. No. 2139 dated 12-8-1972 (Government of India Notification No. X. 11014/12/72-D, dated the 5th June, 1972).

Details of portion of sample or container with name of ingredients from which it is claimed to be made.

Inspector

[See Rule 59(2)]

1. I/We of hereby
 apply for licence to sell by—[†]wholesale
 retail drugs †specified in Schedules

2. ‡The sale and dispensing of drugs will be made under the personal supervision of a qualified person.

(Name) (Qualifications)

3. Categories of drugs to be sold.....

4. §Particulars of storage accommodation for Schedules C and C(1) drugs in the premises referred to above.....

5. A fee of rupees.....
has been credited to Government under the head of account.....

Signature

[See Rule 59(2)]

Application for the grant or renewal of a restricted licence to sell, stock or exhibit for sale, or distribute drugs by retail by itinerant vendors and other dealers who do not engage the services of a qualified person

1. I/We of hereby
 apply for a licence to sell by retail (i) Drugs other than those specified
in Schedules C and C(1) on the premises situated at.....
in Schedules C and C(1) as vendor in the area.....

•Amended under Government of India Notification No. F. 1-16/57-D, dated 15-6-1957.

† Delete whichever is not applicable.

†To be *deleted* if drugs will be sold only by wholesale.

§Required only if products requiring special storage are to be sold.

Drugs specified in Schedules C and C (1) on the premises situated or (ii) Drugs specified in Schedules C and C (1) as vendor in the area at.....
 area.....

2. Sales shall be restricted to such drugs as can be sold without the supervision of a qualified person under the Drugs and Cosmetics Rules.

3. Names or classes of drugs proposed to be sold.....

*4. Particulars of the storage accommodation for the storage of Schedules C and C(1) drugs on the premises referred to above.

†5. The drugs for sale will be purchased from the following dealers and such other dealers as may be endorsed on the licence by the Licensing Authority from time to time.

Name of the dealers.....Licence No.....
 ‡five

6. A fee of rupees _____ has been credited to Government under the head of account.....
 ‡twenty

Date

Signature

****FORM 19-AA**

[See Rule 62C]

Application for grant or renewal of a licence to sell by wholesale or to distribute drugs from a motor vehicle

1. I/We_____of_____ hereby apply for licence to sell by wholesale or to distribute drugs specified in Schedule C and Schedule C(1) and/or drugs other than those specified in Schedule C and Schedule C(1) from the vehicle bearing registration No._____ assigned under the Motor Vehicles Act, 1939.

2. Categories of drugs to be sold/distributed_____

3. A fee of rupees_____has been credited to Government under the head of account_____

*4. Particulars of the storage accommodation for the storage of drugs specified in Schedules C and C(1) on the vehicle referred to above.

Date _____ Signature _____

*Delete if not required.

†Applies only to an itinerant vendor.

‡Rupees five for itinerant vendors and applicant from a village or town having a population of 5,000 or less, and rupees twenty for other restricted licence.

**Added by Govt. of India Notification No. X.11013/7/7C—D&MS, dated the 25th January, 1979.

FORM 19-B

[See Rule 67-A]

*Application for licence to sell, stock or exhibit for sale or distribute
Homoeopathic medicines*

1. I/We..... ofhereby apply for a
*wholesale
licence to sell by.....Homoeopathic medicine on
*retail
the premises situated at.....

†2. The sale and dispensing of Homoeopathic medicines shall be made
under the personal supervision of the following competent person in-charge.

Name.....

3. A fee of rupees..... has been credited to Government under
the head of account.....

Date.. .. Signature.....

FORM 20

[See Rule 61 (1)]

*Licence to sell, stock or exhibit for sale or distribute drugs by retail other
than those specified in Schedules C and C(I).*

1.....is hereby licensed to sell, stock or exhibit
for sale or distribute by retail drugs other than those specified in Schedules C
and C(1) of the Drugs and Cosmetics Rules, 1945, *and to operate a phar-
macy on the premises situated at.....subject to the conditions
specified below and to provisions of the Drugs and Cosmetics Act, 1940
and the Rules thereunder.

2. The licence shall be in force from.....to.....

3. Name(s) of qualified person(s) in charge.....

4. Categories of drugs.....

Date.....

Licensing Authority

Conditions of Licence

1. This licence shall be displayed in a prominent place in a part of the premises open to the public.
2. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder for the time being in force.

*Delete whichever is not applicable.

To be deleted if Homoeopathic medicines will be sold by wholesale.

3. The licensee shall report to the Licensing Authority any change in the qualified staff incharge within one month of such change.
4. No drug shall be sold unless such drug is purchased under cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.
5. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

FORM 20-A

[See Rule 61(1)]

Restricted licence to sell, stock or exhibit for sale or distribute drugs by retail other than those specified in Schedules C and C(1) for itinerant vendors and other dealers who do not engage the services of a qualified person.

1. is hereby licensed to sell, stock or exhibit for sale or distribute on the premises situated at/as vendor in the area..... the following drugs being drugs other than those specified in Schedules C and C(1) of the Drugs and Cosmetics Rules, 1945, subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder.

2. The licence shall be in force from..... to.....

3. The licensee can deal only in such drugs as can be sold without the supervision of a "qualified person" under the Drugs and Cosmetics Rules, 1945.

4. The licensee, if he be an itinerant vendor, shall buy drugs only from the following dealers and such other dealers as may be endorsed on the licence by Licensing Authority from time to time.

Name of the dealer..... Licence No.

Date..... Licensing Authority

Conditions of Licence

1. This licence shall be displayed in a prominent place in a part of the premises open to the public or shall be kept on the person of the vendor who shall produce it on demand by an Inspector or an officer authorised by the State Government in this behalf.

2. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder for the time being in force.

3. No drug shall be sold unless such drug is purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.

4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

FORM 20-B

[See Rule 61(1)]

Licence to sell, stock or exhibit for sale, or distribute by wholesale, drugs other than those specified in Schedules C and C(I)

1. is hereby licensed to sell, stock or exhibit for sale or distribute by wholesale drugs other than those specified in Schedules C and C(1) on the premises situated at.....subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940, and the Rules thereunder.

2. The licence shall be in force from.....to.....

Date

Licence No.

Licensing Authority

Conditions of Licence

1. This licence shall be displayed in a prominent place in a part of the premises open to the public.

2. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder for the time being in force.

*3(i) No drug shall be sold unless such drug is purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.

(ii) No sale of any drug shall be made to a person not holding the requisite licence to sell, stock or exhibit for sale or distribute the drug. Provided that this condition shall not apply to the sale of any drug to—

(a) an officer or authority purchasing on behalf of Government.
or

*Amended by Government of India Notification No. F.1-63/61-D, dated 17th July, 1963.

- (b) a hospital, medical, educational or research institution or a registered medical practitioner for the purpose of supply to his patients, or
- ** (c) a manufacturer of beverages, confectional biscuits and other non-medicinal products, where such drugs are required for processing these products;
4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

@Form 20-BB

(See Rule 62-D)

Licence to sell by wholesale or to distribute drugs other than those specified in Schedule C and Schedule C(1) to the Drugs and Cosmetics Rules, 1945 from a motor vehicle.

1. _____ is hereby licensed to sell by wholesale, or to distribute drugs other than those specified in Schedule C and Schedule C(1) from the vehicle bearing registration No. _____ assigned under Motor Vehicles Act, 1939, subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder.

2. The licence shall be in force from _____ to _____.

3. Categories of drugs.

Date. _____ Licence No. _____

Licensing Authority.

Conditions of Licence.

1. This licence shall be displayed in a prominent place on the vehicle.
2. The licensee shall comply with the provisions of the Drugs and cosmetics Act, 1940 and the Rules made thereunder for the time being in force
- 3 (i) No drugs shall be sold by wholesale or distributed unless such drug is purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.

** Added under Govt. of India. Min. of Health F.P., W.H. & U.D. Notification No. F 1-113/69-D, dated 23-12-1969.

@ Added by Govt. of India Notification No. X. 11013/7/76-D & MS, dated the 25th January, 1979.

(ii) No sale by wholesale or distribution of any drug shall be made to a person not holding the requisite licence to sell, stock, or exhibit for sale or distribute the drug :

Provided that this condition shall not apply to the sale of any drug to :—

- (a) an officer or authority purchasing on behalf of the Government,
or
- (b) a hospital, medical, educational or research institution or a registered medical practitioner for the purpose of supply to his patients, or
- (c) a manufacturer of beverages, confectionary, biscuits and other non-medical products, where such drugs are required for processing these products;

4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

5. The licensee shall inform the Licensing Authority in writing in the event of any change in ownership of the vehicle specified in this licence within seven days of such change”.

†FORM 20-C

[See Rule 67-C]

Licence to sell, stock or exhibit for sale or distribute Homoeopathic medicines by retail

1. is hereby licensed to sell, stock or exhibit for sale or distribute by retail Homoeopathic medicines on the premises situated at subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder.

2. The licence shall be in force from to

3. Name of the competent person in-charge.

Date

Licensing Authority

Conditions of Licence

1. The licence shall be displayed in a prominent place in a part of the premises open to the public.

† Added under Government of India Notification No. F. 1-35/64-D dated 18th August, 1964.

2. The licensee shall comply with the provisions applicable to Homoeopathic medicines under the Drugs and Cosmetics Act, 1940 and the Rules made thereunder for the time being in force.
3. The licensee shall report to the Licensing Authority any change in the competent staff within one month of such change.
- @(4) This licence authorises the sale of Homoeopathic medicines made from one earlier potency up to a quantity of 30ml. at a time.
- ** (5) Where any change in the constitution of the firm takes place, a licensee shall inform the Licensing Authority in writing about the same and the current licence shall be valid only for a period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

*FORM 20-D

[See Rule 67-C]

Licence to sell, stock or exhibit for sale or distribute Homoeopathic medicines by wholesale

1. is hereby licensed to sell, stock or exhibit for sale or distribute by wholesale Homoeopathic medicines on the premises situated at subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder.

2. The licence shall be in force from
 Date Licensing Authority

Conditions of Licence

1. This licence shall be displayed in a prominent place on the premises.
2. The licensee shall comply with the provisions as applicable to Homoeopathic medicines under the Drugs and Cosmetics Act, 1940 and the Rules made thereunder for the time being in force.
3. No sale of any drug shall be made to a person not holding the requisite licence to sell, stock or exhibit for sale or distribute the drug. Provided that this condition shall not apply to the sale of any drug to (a) an authority purchasing on behalf of Government, or (b) a hospital, medical, educational or research institution or a Homoeopathic medical practitioner for the purpose of supply to his patients.

*Added under Govt. of India Notification No. F. 1-35/64-D, dated 18th August, 1964

@Added under Govt. of India, Ministry of Health, F.P., W.H. and U.D. Notification No. F. 1-59/68-D, dated 19th November, 1969.

**Added under G.S.R. No. 665, dated 28-5-1977 (Govt. of India Notification No. X. 11014/2/77-D&MS, dated 6-5-1977).

- @4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence and the current licence shall be valid only for a period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

*FORM 20-E

[See Rule 67-EE]

Certificate of renewal of licence to sell, stock or exhibit for sale or distribute Homoeopathic Medicines

1. Number of licence and date of issue.....

Certified that licence No.....in Form 20-C/20-D granted on the.....to.....for sale of Homoeopathic medicines at the premises situated at.....has been renewed for a period fromto

2. Name of competent person incharge.

Date.....

Licensing Authority.

FORM 21

[See Rule 61(2)]

Licence to sell, stock or exhibit for sale, or distribute by retail drugs specified in Schedules C and C(1)

**1. is hereby licensed to sell, stock or exhibit for sale or distribute by retail the following categories of drugs specified in Schedules C and C (1) to the Drugs and Cosmetics Rules, 1945* and to operate a pharmacy on the premises situated at.....subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder.

2. The licence shall be in force from.....to.....

3. Name(s) of qualified persons in charge.....

- **4. Categories of drugs.....

Date.....

Licence No.....

Licensing Authority

*Delete if not applicable

*Added under Govt. of India, Ministry of Health and Family Planning Notification No. F. I-14/67-D, dated the 3rd February, 1969.

**Amended by S.O. 2139 dated 12-8-1972 (Govt. of India Notification No. X. 11014/12/72-D, dated the 5th June, 1972).

@Added under G.S.R. No. 665, dated 28-5-1977 (Govt. of India Notification No. X. 11014/2/77-D & MS, dated 6-5-1977).

Conditions of Licence

1. This licence shall be displayed in a prominent place in a part of the premises open to the public.
2. The licensee shall report to the Licensing Authority any change in the qualified staff in charge within one month of such change.
3. No drug specified in this licence shall be sold or stocked or exhibited for sale unless such precautions as are published by the Licensing Authority from time to time in the Gazette have been observed throughout the period during which it has been in the possession of the licensee.
4. If the licensee wants to sell, stock or exhibit for sale, or distribute, during the currency of the licence, additional categories of drugs listed in Schedules C and C(1) but not included in this licence, he should apply to the Licensing Authority for the necessary permission. This licence will be deemed to extend to the categories of drugs in respect of which such permission is given. This permission shall be endorsed on the licence by the Licensing Authority.
- *5. No drug shall be sold unless such drug is purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.
6. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

Form 21-A

[See Rule 61(2)]

Restricted licence to sell, stock or exhibit for sale or distribute by retail drugs specified in Schedules C and C(1) for itinerant vendors and dealers who do not engage the services of a qualified person

1. is hereby licensed to sell, stock or exhibit for sale or distribute by retail on the premises situated at/as vendor in the area....
 the following drugs being drugs specified in Schedules C and C(1) to the Drugs and Cosmetics Rules, 1945, subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder.

2. The licence will be in force from.....to.....

3. Particulars of Schedules C and C(1) drugs to be sold.....

4. The licensee, if he is an itinerant vendor, shall buy drugs only from the following dealers and such other dealers as may be endorsed on the licence by the Licensing Authority from time to time.

*Added under Government of India Notification No. F. 1-63/61-D, dated 17th July, 1963.

*Name of the dealer(s)**Licence No.....**Date**Licensing Authority .**Conditions of Licence*

1. This licence shall be displayed in a prominent and conspicuous place in a part of the premises open to the public or shall be kept on the person of the vendor who shall produce it on demand by an Inspector or an officer authorised by the State Government in this behalf.
2. No drug to which this licence applies shall be sold or stocked and exhibited for sale unless such precautions as are published by the Licensing Authority from time to time in the Gazette have been observed throughout the period during which it has been in the possession of the licensee.
3. The licensee shall deal only in such drugs as can be sold without the supervision of a "qualified person" as defined in the Explanation to sub-rule (15) of rule 65 of the Drugs and Cosmetics Rules, 1945.
4. No drug shall be sold unless such drug is purchased under cash or credit memo from duly licensed dealer or duly licensed manufacturer.
5. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

FORM 21-B*[See Rule 61(2)]*

Licence to sell, stock or exhibit for sale or distribute by wholesale drugs specified in Schedules C and C(1)

1. is hereby licensed to sell, stock or exhibit for sale or distribute by wholesale on the premises situated at..... the following categories of drugs specified in Schedules C and C(1) to the Drugs and Cosmetics Rules, 1945.

Categories of drugs

2. This licence shall be in force from..... to.....

3. This licence is subject to the conditions stated below and to the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder.

*Licence No**Date Licensing Authority*

Conditions of Licence

1. This licence shall be displayed in a prominent place in a part of the premises open to the public.
2. No drug to which this licence applies shall be sold or stocked and exhibited for sale unless the precautions as are published by the Licensing Authority from time to time in the Gazette have been observed throughout the period during which it has been in the possession of the licensee.
3. If the licensee wants to sell, stock and exhibit for sale or distribute during the currency of the licence additional categories of drugs listed in Schedules C and C(1) but not included in this licence, he should apply to the Licensing Authority for the necessary permission. This licence will be deemed to extend to the categories of drugs in respect of which such permission is given. This permission shall be endorsed on the licence by the Licensing Authority.
- *4. (i) No drug shall be sold unless such drug is purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.

(ii) No sale of any drug shall be made for purposes of resale to a person not holding the requisite licence to sell, stock or exhibit for sale or distribute the drug.
Provided that this condition shall not apply to the sale of any drug to—
 - (a) an officer or authority purchasing on behalf of Government, or
 - (b) a hospital, medical, educational or research institution or a registered medical practitioner for the purpose of supply to his patients, or
 - ** (c) a manufacturer of hydrogenated vegetable oils, beverages, confectionary and other non-medicinal products, where such drugs are required for processing these products.
5. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

*Added under Government of India Notification No. F. 1-63/61-D, dated 17th July 1963.

**Added under Govt. of India, Ministry of Health, F.P., W.H., and U.D. Notification No. F. 1-113/69-D, dated 23-12-1969.

****FORM 21-BB**

(See rule 62-D)

Licence to sell by wholesale or to distribute drugs specified in Schedule C and Schedule C(1) to the Drugs and Cosmetics Rules, 1945 from a motor vehicle.

1. _____ is hereby licensed to sell by wholesale, or to distribute drugs specified in Schedule C and Schedule C(1) from the vehicle bearing registration No. _____ assigned under Motor Vehicles Act, 1939, subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder.

2. The licence shall be in force from _____ to _____.

3. Categories of drugs

Date _____

Licence No. _____

Licensing Authority

Conditions of licence

1. This licence shall be displayed in a prominent place on the vehicle.
2. No drugs to which this licence applies shall be sold by wholesale or distributed unless the precautions as are published by the Licensing Authority from time to time in the Official Gazette have been observed throughout the period during which it has been in the possession of the licensee.
3. If the licensee wants to sell by wholesale or distribute during the currency of the licence, additional categories of drugs listed in Schedule C and Schedule C(1) *not* included in this licence, he shall apply to the Licensing Authority for necessary permission. This licence shall be deemed to extend to the categories of drugs in respect of which such permission is given. This shall be endorsed on the licence by the Licensing Authority.
4. (i) No drugs shall be sold by wholesale or distributed unless such drug is purchased under a cash or credit memo from a duly licensed manufacturer.
- (ii) No sale for wholesale or distribution of any drug shall be made for the purpose of resale to a person, not holding the requisite licence to sell, stock or exhibit for sale or distribute the drug :

Provided that this condition shall not apply to the sale of any drug to.—

- (a) an officer or authority purchasing on behalf of the Government,
or

(b) a hospital, medical, educational or research institution or a registered medical practitioner for the purpose of supply to his patients, or

(c) a manufacturer of hydrogenated vegetable oils, beverages, confectionary and other non-medical products, where such drugs are required for processing their products.

5. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

6. The licensee shall inform the Licensing Authority in writing in the event of any change in the ownership of the vehicle specified in this licence within seven days of such change.

FORM 21-C

[See Rule 63-A]

Certificate of renewal of licence to sell, stock or exhibit for sale or distribute drugs

Number of licence and date of issue

1. Certified that licence No. in Form 20, 20-A, 20-B, 21, 21-A, 21-B. granted on the to for sale of the following drugs at the premises situated at has been renewed for a period from to

2. Categories or particulars of drugs

3. Name(s) of qualified person(s) incharge

Date

Licensing Authority

**FORM 21-CC

(See rule 63-B)

Certificate of renewal of licence to sell by wholesale or to distribute drugs from a motor vehicle.

Number of licence and date of issue_____

1. Certified that licence No. _____ in Form 20-BB or Form 21-BB granted on the _____ to _____ for sale by wholesale or distribution of the following drugs from the vehicle _____

bearing registration No. _____ assigned under the
Motor Vehicles Act, 1939 has been renewed for a period from _____
to _____.

2. Categories of the drugs : _____

Date _____

Licensing Authority.

FORM 24

[See Rule 69]

*Application for the grant of or renewal of a licence to manufacture for sale
drugs other than those specified in Schedules C and C (1)*

1. I/We of hereby
apply for the grant/renewal of a licence to manufacture on the premises
situated at the following drugs being drugs other than
those specified in Schedules C and C(1) to the Drugs and Cosmetics Rules,
1945.

2. Names of drugs categorized according to Schedule M.
.....

3. Names, qualifications and experience of technical staff employed for
manufacture and testing.

4. A fee of rupees has been credited to Govern-
ment under the head of account
Date Signature

NOTE.—The application should be accompanied by a plan of the premises.

FORM 24-A

[See Rule 69-A]

*Application for grant or renewal of a loan licence to manufacture for sale
drugs other than those specified in Schedules C and C(1)*

1. I/We* of† hereby
apply for the grant/renewal of a loan licence to manufacture on the premises

*Enter here the name of the proprietor, partners or Managing Director as the case
may be.

†Enter here the name of the applicant firm and the address of the principal place of
business

**Added by Good of India Notification No. X. 11013/7/76-D & MS, dated the 25th
January, 1979.

situated at.....C/o†
the undermentioned drugs, other than those specified in Schedules C and C(1) to the Drugs and Cosmetics Rules.

Names of drugs (each substance to be separately specified).

2. The names, qualifications and experience of the expert staff actually connected with the manufacture and testing of the specified products in the manufacturing premises.

3. I/We enclose

(a) A true copy of a letter from me/us to the manufacturing concern whose manufacturing capacity is intended to be utilised by me/us.

(b) A true copy of a letter from the manufacturing concern that they agree to lend the services of their expert staff, equipment and premises for the manufacture of each item required by me/us and that they will analyse every batch of finished product and maintain the registers of raw materials, finished products and reports of analysis separately in this behalf.

(c) Specimens of labels, cartons of the products proposed to be manufactured.

4. A fee of rupees has been credited to Government under the head of account.....

Date.....

Signature

†Enter here the name and address of the manufacturing concern where the manufacture will be actually carried out and also the Licence number under which the latter operates.

FORM 24-B

[See Rule 69]

Application for grant or renewal of a licence to repack for sale or distribution of drugs, being drugs other than those specified in Schedules C and C(1)

1. I/We.....of hereby apply for grant/renewal of a licence to repack the following drugs at the premises situated at.....

2. Names of the drugs to be repacked.....

3. Name, qualification and experience of competent staff.....

4. A fee of rupees forty has been credited to Government under the head of account.....

Date

Signature of applicant

NOTE.—The application shall be accompanied by a plan of the premises.

***FORM 24-C**

[See Rule 85-B]

Application for the grant or renewal of a licence to manufacture for sale of Homoeopathic medicines or a licence to manufacture potentised preparations from back potencies by licensees holding licence in Form 20-C

1. I/We..... of holder of licence No. in Form 20-C hereby apply for the grant/renewal of licence to manufacture Homoeopathic mother tinctures/potentised preparations on the premises situated at

2. Names, qualifications and experience of technical staff employed for manufacture and testing of Homoeopathic medicines.

3. A fee of rupees has been credited to Government under head of account
.....

Date.....

Signature.....

NOTE 1.—Delete whichever portion is not applicable.

2.—The application should be accompanied by a plan of the premises.

****FORM 24-D**

[See Rule 153]

Application for the grant/renewal of a licence to manufacture for sale of Ayurvedic/Siddha or Unani drugs

1. I/We..... of hereby apply for the grant/renewal of a licence to manufacture Ayurvedic (including Siddha) or Unani drugs on the premises situated at.....

2. Names of drugs to be manufactured (with details)

3. Names, qualifications and experience of technical staff employed for manufacture and testing of Ayurvedic (including Siddha) or Unani drugs

4. A fee of rupees has been credited to the Government under the head of account..... and the relevant Treasury Challan is enclosed herewith.

Date

Signature

(applicant)

NOTE.—The application should be accompanied by a Plan of the premises.

**Added under Govt. of India, Ministry of Health, F.P., W.H. and U.D. Notification No. 1-23/67-D, dated 2-2-1970.

*Amended by Govt. of India, Ministry of Health, F.P., W.H. and U.D. Notification No. F.1-598-D, dated 19th November, 1969.

@FORM 24-E

[See Rule 154-A]

**Application for grant or renewal of a loan licence to manufacture for sale
Ayurvedic (including Siddha) or Unani Drugs**

1. I/We* of†
 hereby apply for the grant/renewal of a
loan licence to manufacture Ayurvedic (including Siddha) or Unani Drugs
on the premises situated at

 C/o**

2. Names of drugs to be manufactured (with details).

3. The names, qualifications and experience of technical staff actually
 connected with the manufacture and testing of Ayurvedic (including Siddha)
 or Unani drugs in the manufacturing premises.

4. I/We enclose.

(a) A true copy of a letter from me/us to the manufacturing concern whose manufacturing capacity is intended to be utilised by me/us.

(b) A true copy of a letter from the manufacturing concern that they agree to lend the services of their competent technical staff, equipment and premises for the manufacture of each item required by me/us and that they shall maintain the registers of raw materials and finished products separately in this behalf.

(c) Specimen of labels, cartons of the drugs proposed to be manufactured.

4. A fee of Rs. has been credited to Government under the head of account and the relevant Treasury Challan is enclosed herewith.

Date

Signature

(applicant)

Enter here the name of the proprietor, partners or Managing Director as the case may be.

†Enter here the name of the applicant firm and the address of the principal place of business.

**Enter here the name and address of the manufacturing concern where the manufacture will be actually carried out and also the licence number under which the letter operates.

@Added by GSR. No. 376(E) dated the 20th July, 1978 (Govt. of India Notification No. X.11013/2/77-D MS& PFA dated the 20th July, 1978).

FORM 25

[See Rule 70]

Licence to manufacture for sale of drugs other than those specified in the Schedules C and C(1)

Number of Licence and date of issue.....

1. is hereby licensed to manufacture the following categories of drugs being drugs other than those specified in Schedules C and C(1) to the Drugs and Cosmetics Rules, 1945, on the premises situated at..... under the direction and supervision of the following expert staff.

(a) Expert staff (Name).

(b) Names of Drug (each item to be separately specified)

2. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence, subject to the conditions applicable to licence for sale.

3. The licence shall be in force from to

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date.....

Signature.....

Designation.....

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. Any change in the expert staff named in the licence shall be forthwith reported to the Licensing Authority.
3. If the licensee wants to manufacture for sale additional items of drugs not included above he should apply to the Licensing Authority for the necessary endorsement as provided in rule 69(5). This licence will be deemed to extend to the categories so endorsed.
4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

FORM 25-A

[See Rule 70-A]

Loan licence to manufacture for sale drugs other than those specified in Schedules C and C(1)

1. Number of licence and date of issue
2. of is hereby granted a loan licence to manufacture the following drugs being drugs other than those specified in Schedules C and C(1) to the Drugs and Cosmetics Rules, 1945, on the premises situated at C/o under the direction and supervision of the following expert staff.

(a) Expert staff (Names)

(b) Names of drugs

3. The licence authorizes the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence subject to the conditions applicable to licences for sale.

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date

Signature

Designation

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced on the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. Any change in the expert staff named in the licence shall be forthwith reported to the Licensing Authority.
3. If the licensee wants to undertake during the currency of the licence the manufacture for sale of additional drugs he should apply to the Licensing Authority for the necessary endorsement to the licence as provided in rule 69-A. This licence will be deemed to extend to the drugs so endorsed.
4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

*FORM 25-B

[See Rule 70]

Licence to repack for sale or distribution of drugs being drugs other than those specified in Schedules C and C(1)

Number of licence and date of issue

1 of is hereby granted a licence to repack the following drugs for sale or distribution on the premises situated at under the supervision of the following competent staff.

(a) Names of drugs to be repacked.

(b) Names of competent staff.

2. The licence shall be in force from to

3. The licence authorises the sale by way of wholesale dealing by the licensee and storage for sale by the licensee of the drugs repacked under the licence subject to conditions applicable to licences for sale.

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date Signature

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the licensed premises and shall be produced on the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. Any change in the competent staff named in the licence shall be forthwith reported to the Licensing Authority.
3. If the licensee wants to repack for sale or distribution additional items he should apply to the Licensing Authority for the necessary endorsement to this licence. This licence shall be deemed to extend to only those items so endorsed.
4. The drugs repacked under this licence shall bear on their label, apart from other particulars required by these Rules, the name and address of the licensee and the number of the licence under which the drug is repacked preceded by the words "Rpg. Lic. No.".
5. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

*Added under Government of India Notification No. F. 1-22/59-D, dated 9-4-1960.

*FORM 25-C

[See Rule 85-D]

Licence to manufacture for sale Homoeopathic medicines

Number of Licence and date of issue

@1. I, who holds a licence in Form 20-C is hereby licensed to manufacture Homoeopathic mother tinctures/potentised preparations on the premises situated at under the direction and supervision of the following technical staff.

Technical Staff (Names)

2. The licence shall be in force from to

3. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date

Signature

Designation

@Delete the words who holds a licence in Form 20-C in case this is not applicable.

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. Any change in the technical staff named in the licence shall be forthwith reported to the Licensing Authority.
- **3. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

*Added under Government of India Notification No. F. 1-36/64-D, dated 18th August 1964.

@Amended and added by Govt. of India, Ministry of Health, F.P., W.H. and U.D. Notification No. F. 1-59/68-D, dated the 19th November, 1969.

**Added by S.O. No. 903 dated 28-2-1976 (Govt. of India Notification No. X.11013/2/75-D&MS dated the 10th February, 1976).

FORM 25-D*[See Rule 154]*****Licence to manufacture for sale of Ayurvedic (including Siddha) or Unani drugs***

No. of Licence

1. is/are hereby licensed to manufacture the following Ayurvedic (including Siddha) or Unani drugs on the premises situated at under the direction and supervision of the following technical staff :—

(a) Technical staff (Names).

(b) Names of drugs (each item to be separately specified).

2. The licence shall be in force from to

3. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date of Issue***Signature******Designation******Conditions of Licence***

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. Any change in the technical staff named in the licence shall be reported forthwith to the Licensing Authority.
3. This licence shall be deemed to extend to such additional items as the licensee may intimate to the Licensing Authority from time to time, and as may be endorsed by the Licensing Authority.
4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

*Added under Government of India, Ministry of Health, F.P., W.H. and U.D. Notification No. 1-23/67-D, dated 2-2-1970.

*FORM 25-E

[See Rule 154-A]

Loan licence to manufacture for sale Ayurvedic (including Siddha) or Unani Drugs

1. Number of licence

2. of is hereby granted a loan licence to manufacture for sale Ayurvedic (including Siddha) and Unani drugs, on the premises situated at C/o. under the direction and supervision of the following expert technical staff.

(a) Technical Staff (Names)

(b) Names of drugs (each item to be separately specified)

3. The licence shall be in force from to

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date of Issue

Signature

Designation

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector, appointed under the Drugs and Cosmetics Act, 1940.
2. Any change in the technical staff named in the licence shall be reported forthwith to the Licensing Authority.
3. This licence shall be deemed to extend to such additional items as the licensee may intimate to the Licensing Authority from time to time, and as may be endorsed by the Licensing Authority.
4. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

* Added by GSR No. 376(E), dated the 20th July, 1978 (Govt. of India Notification No. 11013/2/ 77-DMS&PFA, dated the 20th July, 1978).

FORM 26

[See Rules 73 and 83]

Certificate of renewal of licence to manufacture for sale drugs

1. Certified that licence No. granted on the
 to for the manufacture of the following categories of
 undermentioned drugs
 drugs being drugs other than those specified in Schedules C and C(1)
 being drugs covered by Schedules C and C(1) to the Drugs and Cosmetics
 to the Drugs and Cosmetics Rules, 1945
 Rules, 1945 at the premises situated
 at has been renewed from

*Categories of drugs

Names of drugs

2. Name(s) of approved expert staff

Signature

Date

Designation

*Delete whatever portion is not required.

FORM 26-A

[See Rules 73-A and 83-A]

Certificate of renewal of loan licence to manufacture for sale drugs

1. Certified that loan licence No. granted on the
 to for the manufacture of
 *drugs other than drugs in Schedules C and C(1) to the Drugs and
 under mentioned drugs*, being drugs specified in Schedules C and
 C(1) to the Drugs and Cosmetics Rules, 1945 at the premises situated
 Cosmetics Rules, 1945

at C/o has been renewed
 from to

2. Names of the approved expert staff.

Signature

Date

Designation

*Names of drugs (each substance to be separately specified).

***FORM 26-B**

[See Rule 73-B]

Certificate of renewal of licence to repack for sale or distribution of drugs being drugs other than those specified in Schedules C and C(1)

1. Certified that licence No. granted on the
to for the repacking of the following drugs at the
premises situated at has been renewed from
to

Names of drugs to be repacked

2. Names of competent staff

Signature

Date

Designation

FORM 26-C

(See Rule 85-G)

Certificate of renewal of licence to manufacture for sale of Homoeopathic medicines

1. Certified that licence No. granted on the
..... to for the manufacture for sale of
the Homoeopathic mother tinctures/potentised preparations at the premises
situated at has been renewed
for a period from the to

2. Names of technical staff

Signature

Date

Designation

****FORM 26-D**

(See Rule 155)

*Certificate of renewal of licence to manufacture for sale of
Ayurvedic/Siddha or Unani drugs*

1. Certified that licence No. granted on
the to Shri/Messrs. for the manufacture of
Ayurvedic/Siddha/Unani drugs at the premises situated at
..... has been
renewed from to

2. Name of technical staff

@3. Names of drugs (each item to be separately specified).

Signature

Date

Designation

*Added under Government of India Notification No. F. 1-22/59-D, dated 9th April, 1964.

**Added under Government of India, Ministry of Health, F.P., W.H. and U.D. Notification No. 1-23/67—D, dated 2-2-1970.

@ Added by G.S.R. No. 376(E), dated the 20th July, 1978. (Govt. of India Notification No. X. 11013/2/77-DMS & PFA, dated the 20th July, 1978.)

*FORM 26-E

(See Rule 155-A)

*Certificate of renewal of loan licence to manufacture for sale of Ayurvedic/
Siddha/or Unani Drugs*

1. Certified that loan Licence No. granted
on the to
for the manufacture of Ayurvedic/Siddha/or Unani drugs at the premises
situated at C/o has been
renewed from to

2. Name of technical staff
Date

Signature

Designation

FORM 27

*Application for grant or renewal of a licence to manufacture for sale drugs
specified in Schedules C and C(1)*

1. I/We hereby apply for the grant/
renewal of a licence to manufacture on the premises situated at
..... the undermentioned drugs, being drugs
specified in Schedule C and/or C(1) to the Drugs and Cosmetics Rules,
1945.

Names of drugs.

(each item to be separately specified).

2. The names, qualifications and experience of the expert staff responsi-
ble for the manufacture and testing of the above mentioned drugs.

(a) Name(s) of staff responsible
for test.....

(b) Name(s) of staff responsible
for manufacture

3. The premises and plan are ready for inspection

Will be ready for inspection on

4. A fee of rupees and an inspection fee
of rupees has been credited to
Government under the head of account.

Date Signature

Designation

NOTE.—The application shall be accompanied by a plan of the premises.

*Added by GSR No. 376 (E), dated the 20th July, 1978 Govt. of India Notifica-
tion No. X. 11013/2/77-DMS&PFA, dated the 20th July, 1978).

FORM 27-A

[See Rule 75-A]

Application for grant or renewal of a loan licence to manufacture for sale drugs specified in Schedules C and C(1)

1. I/We* of† hereby apply for the grant/renewal of Loan licence to manufacture on the premises situated at C/o ‡ the undermentioned drugs, being drugs specified in Schedules C and C(1) to the Drugs and Cosmetics Rules.

Names of drugs (each substance to be separately specified).

2. The names, qualifications and experience of the expert staff actually connected with the manufacture and testing of the specified products in the manufacturing premises.

- (a) Name(s) of expert staff responsible for manufacture
- (b) Name(s) of the expert staff responsible for testing

3. I/We ~~enclose~~

- (a) A true copy of a letter from me/us to the manufacturing concern whose manufacturing capacity is intended to be utilised by me/us.
- (b) A true copy of a letter from the manufacturing concern that they agree to lend the services of their expert staff, equipment and premises for the manufacture of each item required by me/us and that they will analyse every batch of finished products and maintain the registers of raw materials, finished products and reports of analysis separately on this behalf.
- (c) Specimens of labels, cartons of the products proposed to be manufactured.

4. A fee of rupee has been credited to Government under the head of account

Date

Signature
Designation

*Enter here name of the proprietor, partners of Managing Director, as the case may be.

†Enter here name of the applicant firm and the address of the principal place of business.

‡Enter here the name and address of the manufacturing concern where the manufacture will be actually carried out and also the licence number under which the latter operates.

FORM 28-A

[See Rule 76]

Licence to manufacture for sale drugs specified in Schedules C and C(1)

Number of licence and date of issue

1. is hereby licensed to manufacture at the premises situated at the the following drugs, being drugs specified in Schedules C and C(1) to the Drugs and Cosmetics Rules, 1945.

Names of drugs

2. Names of approved expert staff

3. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence subject to the conditions applicable to licences for sale.

4. The licence will be in force from to

5. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date of issue Signature

Designation

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. If the licensee wishes to undertake during the currency of the licence the manufacture of any drug specified in Schedules C and C(1) not included above, he should apply to the Licensing Authority for the necessary endorsement as provided in rule 75(3). This licence will be deemed to extend to the items so endorsed.

3. Any change in the expert staff shall be forthwith reported to the Licensing Authority.

4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

FORM 28-A

[See Rule 76-A]

Loan licence to manufacture for sale drugs specified in Schedules C and C(1)

1. Number of licence and date of issue

2. of is hereby granted a loan licence to manufacture on the premises situated at C/o the following drugs being drugs specified in Schedules C and C(1) to the Drugs and Cosmetics Rules, 1945.

Names of Drugs

3. Names of approved expert staff

*3A. The licence shall be in force from to

4. The licence authorizes the sale by way of wholesale dealing by the licensee and storage for sale by the licensee of the drugs manufactured under the licence subject to the conditions applicable to licence for sale.

5. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date of issue Signature

Designation

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. If the licensee wishes to undertake during the currency of the licence to manufacture any drugs specified in Schedule C and/or C(1) not included above, he should apply to the Licensing Authority for the necessary endorsement as provided in rule 75-A. This licence will be deemed to extend to the items so endorsed.

3. Any change in the expert staff shall be forthwith reported to the Licensing Authority.

4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

*Added under Government of India Notification No. F. 1-10/62-D, dated 11th April, 1964.

FORM 29

[See Rule 89]

Licence to manufacture drugs for purposes of examination, test or analysis

1. of is hereby licensed to manufacture the drugs specified below for purposes of examination, test or analysis at

2. This licence is subject to the conditions prescribed in Part VIII of the Drugs and Cosmetics Rules, 1945.

3. This licence shall be in force for one year from the date specified below.

Names of drugs

Date *Licensing Authority*

FORM 30

[See Rule 90]

Application for licence to manufacture drugs for purposes of examination, test or analysis

I of by occupation hereby apply for a licence to manufacture the drugs specified below for purposes of examination, test or analysis at and I undertake to comply with the conditions applicable to the licence.

Names of drugs

Date *Signature*

Form 31

[See Rule 139]

Application for grant or renewal of a licence to manufacture cosmetics for sale

1. I/We of hereby apply for the grant/renewal of a licence to manufacture on the premises situated at the following cosmetics :—

2. Names of 'Cosmetics'

3. Names, qualifications and experience of technical staff employed for manufacture and testing

4. A fee of rupees has been credited to Government under the head of account

Date *Signature*

NOTE.—The application should be accompanied by a plan of the premises.

*FORM 31-A

(See Rule 138-A)

Application for grant or renewal of loan licence to manufacture cosmetics

1. I/We of hereby apply

1. I/We of hereby apply
for grant/renewal of a loan licence to manufacture cosmetics for sale
on the premises situated at C/o.....
the following cosmetics :—

2. Names of Cosmetics.....

3. The names, qualifications and experience of the expert staff actually
connected with the manufacture and testing of the specified products in
the manufacturing premises.

4. I/We enclose

(a) A true copy of a letter from me/us to the manufacturing
concern whose manufacturing capacity is intended to be
utilised by me/us.

(b) A true copy of a letter from the **manufacturing concern that
they agree to lend the services of their expert staff, equipment
and premises for the manufacture of each item required by me/
us and that they will analyse every batch of and maintain the
registers of raw materials, finished products and reports of
analysis separately in this behalf.

(c) specimens of labels, cartons of the products proposed to be
manufactured.

5. A fee of rupees has been credited to Government
under the head of Account

Date..... Signature

FORM 32

[See Rule 140]

Licence to manufacture cosmetics for sale

Number of Licence and date of issue

1. is hereby licensed to manufacture on the premises
situated at the following cosmetics under the
supervision of the following technical staff :—

(a) Names of cosmetics

(b) Names of the technical staff

*Added by G.S.R. No. 444 dated 28-4-1973 (Government of India Notification No.
X-11014/4/72-D (Pt.) dated the 31st March, 1973).

**Enter here the name and address of the manufacturing concern where the manu-
facture will be actually carried out and also their licence number.

2. The licence shall remain in force from to
(both days inclusive).

3. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Drugs and Cosmetics Rules, 1945.

Date

Signature

Designation

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. Any change in the technical staff shall be forthwith reported to the Licensing Authority.

3. If the licensee wants to manufacture for sale additional items he should apply to the Licensing Authority for the necessary endorsement to the licence as provided in rule 138(3). This licence shall be deemed to extend to the cosmetics so endorsed.

*4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

****FORM 32-A**

[See Rule 139-B]

Loan licence to manufacture cosmetics for sale

1. Number of licence and date of issue

2. of is hereby granted a loan licence to manufacture the following cosmetics on the premises situated at C/o under the direction and personal supervision of the following technical staff:—

(a) Names of the technical staff.

(b) Names of cosmetics.

3. The licence shall remain in force from to

4. The licence is subject to the conditions stated below and to such other conditions as are specified in the rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date

Signature

Designation

*Added by S. O Np 903 dated 28-2-1976 (Govt. of India Notification No. X. 11013/2/75-D&MS, dated the 0th February, 1976).

**Added by G.S.R. No. 444 dated 28-4-1973 (Govt. of India Notification No. X-11014/4/72-D (Pt.) dated the 31st March, 1973).

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. Any change in the technical staff shall be forthwith reported to the Licensing Authority.

3. If the licensee wants to manufacture for sale additional items he should apply to the Licensing Authority for the necessary endorsement to the licence as provided in rule 138-A(5). This licence shall be deemed to extend to the cosmetics so endorsed.

FORM 33

[See Rule 141]

Certificate of renewal of licence to manufacture cosmetics for sale

1. Certified that licence No. granted on the to for the manufacture for sale of the following cosmetics at the premises situated at has been renewed from and shall expire on.....

1. Names of cosmetics.

2. Names of the technical staff.

Date

Signature.....

Designation.....

*FORM 33-A

[See Rule 141-A]

Certificate of renewal of loan licence to manufacture Cosmetics for sale

1. Certified that loan licence No. granted on the to for the manufacture for sale of the following cosmetics at the premises situated at C/o has been renewed from to

1. Names of cosmetics.

2. Names of technical staff.

Date

Signature.....

Designation.....

*Added by G.S.R. No. 444 dated 28-4-1973 (Govt. of India Notification No. 11014, 4/72-D (Pt.) dated the 31st March, 1973).

FORM 34

[See Rules 131 and 150]

Certificate of test or analysis of cosmetic by the Central Drugs Laboratory or the Government Analyst

1. Name of the officer or Inspector from whom received
2. Serial number and date of the Officer's/Inspector's memorandum
.....
3. Number of sample
4. Date of receipt
5. Name of the Cosmetic purporting to be contained in the sample
.....
6. Condition of seals on the package
7. *Results of test or analysis :*

The sample of cosmetics—

- (a) contains a prescribed colour only.
does not contain a prescribed colour.
- (b) does not contain harmful ingredients.
contains harmful ingredients.
- (c) conforms to claims made on the label as to the
nature and quality of the cosmetic.
does not conform to claims made on the label as to
the nature and quality of the cosmetic.
- (d) does not contain Lead or Arsenic compounds used in
colouring.
contains Lead or Arsenic compounds used in
colouring.

Date

Director,

Central Drugs Laboratory/Government Analyst.

@FORM 35

(See rules 65, 74, 74A, 78, 85H, 142 and 142-A)

Form in which the Inspection Book shall be maintained

(A) The cover of the Inspection Book shall contain the following particulars, namely :—

1. The name and address of the Licensee
2. Licence number and the date upto which the licence is valid
.....

(B) (i) The pages of the Inspection Book shall be serially numbered and duly stamped by the Licensing Authority. The pages,

@Added under Government of India, Ministry of Health, F.P. and U.D. Notification No. F. 1-14/68-D, dated 26-10-1968.

other than the first and the last pages, shall have the following particulars :—

Name and designation of the Inspector who inspects the premises of the Licensee.....

Date of Inspection

Observations of the Inspector

Signature of the Inspector

- (ii) The first and last pages of the Inspection Book shall be endorsed by the Licensing Authority with the following words, namely :—

Inspection Book maintained by M/s.

situated at.....for licence number.....

.....in Form.....

under Drugs and Cosmetic Rules.

Seal and Signature of the
Licensing Authority.

- Notes.*— (i) Printed copy of the Inspection Book may be obtained by the licensee from the Licensing Authority on payment.
- (ii) The Inspection Book shall be maintained at the premises of the Licensee.
- (iii) The observations made by the Drugs Inspector shall be in triplicate. The original copy shall be retained in the Inspection Book to be maintained in the premises of the Licensee. The duplicate copy shall be sent to the Licensing Authority. The triplicate copy shall be taken as record by the Inspector.

****FORM 36**

(See rule 150-B)

Application for grant or renewal of approval for carrying out tests on drugs/cosmetics or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of drugs/cosmetics

(1) I/We of hereby, apply for the grant or renewal of approval for carrying out tests of identity, purity, quality and strength on the following categories of drugs/items of cosmetics or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of drugs/cosmetics.

(2) *Categories of drugs, items of cosmetics :—

- (a) Drugs other than those specified in Schedule C and C(1) and also excluding Homoeopathic Drugs :—

1. Crude vegetable drugs.
2. Mechanical contraceptives.
3. Surgical dressings.
4. Drugs requiring the use of Ultraviolet/Infra Red Spectrophotometer or Chromatography.
5. Disinfectants.

*Delete whichever is not applicable.

**Added under Govt. of India, Ministry of Health & F. W. Notification No. X. 11014/77 76-D & MS, dated 23-8-1977.

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6. Other drugs.

(b) Drugs specified in Schedule C and C(1) :—

1. Sera, Vaccines, Antigens, Toxins, Antitoxins, Toxoids, Bacteriophages and similar Immunological Products.
2. Antibiotics.
3. Vitamins.
4. Parenteral preparations.
5. Sterilised surgical ligature/suture.
6. Drugs requiring the use of animals for their test.
7. Drugs requiring microbiological tests.
8. Drugs requiring the use of Ultraviolet/Infra Red Spectrophotometer or Chromatography.
9. Other drugs.

(c) Homoeopathic drugs.

(d) Cosmetics.

(3) Name, qualifications and experience of expert staff employed for testing and the person-in-charge of testing.

(4) List of testing equipments provided.

(5) I/We enclose a plan of the testing premises showing the location and area of the different sections thereof.

(6) An inspection fee of rupees has been credited to Government under the Head of Account

Date

Signature

FORM 37

(See Rule 150-C)

Approval for carrying out tests on drugs/cosmetics and raw materials used in their manufacture on behalf of licensees for manufacture for sale of drugs/cosmetics

Number of approval and date of issue :

(1) Approval is hereby granted to for carrying out tests for identity, purity, quality and strength on the following categories of drugs/items of cosmetics and the raw materials used in the manufacture thereof on the premises situated

Categories of drugs/items of cosmetics.

(2) Names of approved expert staff employed for testing and the person-in-charge of testing.

(3) The approval shall be in force from to

(4) The approval is subject to the conditions stated below and such other conditions as may be specified in the rules for the time being in force under the Act.

Date.....

Signature.....

Designation.....

Conditions of Approval

(1) This approval and any certificate of renewal in Form 38 shall be kept in the approved premises and shall be produced at the request of the Inspectors appointed under the Act.

(2) If the approved institution wishes to undertake during the currency of the approval the testing of any other category of drugs or items of cosmetics it should apply to the approving authority for necessary endorsement as provided in rule 150-B. This approval will be deemed to extend to the items so endorsed.

(3) Any change in the analytical staff or in the person-in-charge of the testing shall be forthwith reported to the approving authority.

FORM 38

(See rule 150-J)

Certificate of renewal of approval for carrying out tests on drugs/cosmetics and raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of drugs/cosmetics

(1) Certified that approval number..... granted on the for carrying out tests of identity, purity, quality and strength on the following categories of drugs/items of cosmetics and the raw materials used in the manufacture thereof at the premises situated at has been renewed from to

Categories of drugs/items of cosmetics.

(2) Names of approved expert staff and person-in-charge of testing.

.....

.....

Date.....

Signature.....

Designation.....

FORM 39

[See Rule 150-E(f)]

Report of test or analysis by approved institution.

(1) Name of manufacturer from whom sample received together with his manufacturing licence number under the Act and under the Rules made thereunder.

(2) Reference number and date of the letter from the manufacturer under which the sample was forwarded.

(3) Date of receipt of the sample.

(4) Name of drug/cosmetics/raw material purporting to be contained in the sample.

(5) Details of raw material/final product in bulk/final product (in finished pack)* as obtained from the manufacturer :

(a) Original manufacturer's name (in the case of raw materials and drugs repacked).

(b) Batch number.

(c) Total quantity represented by sample.

(d) Date of manufacture, if any.

(e) Date of expiry, if any.

(6) Results of test or analysis with protocols of test or analysis applied.

In the opinion of the undersigned, the sample referred to above is **of standard quality/is not of standard quality* as defined in the Act and the Rules made thereunder for the reasons given below.

Date.....
Signature of Person-in-charge of testing

Note :—Final product includes repacked material.

*Delete whichever is not applicable.

**SCHEDULE B

[See Rules 7 and 48]

Fees for test or analysis by the Central Drugs Laboratory or the Government Analyst

1. Fees for drugs including hormones etc. requiring biological assay.

	Rs.
Adrenocorticotrophic Hormone	200
Digitalis	200

**Amended by Min. of Health & F.W. Notification No. X. 11013/2/78-LMS & IFA, dated 26-8-1978.

	Rs.
Strophanthus	200
Pituitory (Posteriorlobe) Extract	100
Adrenaline preparations	100
Thyroid	200
Sex gland preparations	200
Ovarial	200
Luteal	200
Orchis	200
Heparin	150
Insulin and insulin combination (prolonged action)	*400 to 1000
Organic arsenicals, neo rsphenamine etc.	*75 to 100
Protamine sulphate	150
Test for sterility	50
Abnormal toxicity or undue toxicity or safety test	75
Determination of lethal doses LD 50 to LD 100 on Mice	250
Pyrogen test	60
Antibiotics (bio-assay)	75
(Chemical test for each ingredients)	50
Disinfectants	100
Surgical sutures (depending on the number of tests to be carried out)	50 to 100
Depressor or Histamine like substances test	75
Hyaluronidase	100
Any other test requiring animal experimentation	50
Microbiological assay	75
Microscopic examination	25
Chemical tests and Assays :	25
Identification test	
Disintegration of tablets and capsules	10
(a) Ordinary	20
(b) Sugar coated	40
(c) Enteric coated	30
Physicochemical Assays	
Tests other than assay (limit tests for impurities, ash content, total solids, acid value, iodine value, Saponification value, loss on drying etc.)	10
for each test	25
Optical rotation	25
Refractive index	
Physical tests (solubility, pH, uniformity of weight, physical constants etc.)	5
for each test	30
Water (Karl Fisher)	25
Heavy metals	25
Arsenic test	25
Paper chromatography	30
Thin layer chromatography	

	Rs.
Column chromatography	25
Gas liquid chromatography	100
Infra Red Identification	50
Polymorph test (Content of Polymorph-A in Chloramphenicol Palmitate) .	200
Other miscellaneous tests	*25 to 100
II. Fees for sera and vaccines :	
Sera	
(a) Examined according to specifications of pharmacopoeia	150
(b) Determination that sample is up to titre specified	100
Vaccine	
(a) Examination in which animal test is employed	*100 to 300
(b) Examination in which animal test is not employed	50
Diagnostic toxins :	
(a) Identification test	50
(b) Potency test	200
Diagnostic Sera, Potency and Acidity tests Diphtheria, Pertussis and Tetanus products	
(a) Potency of Pertussis fraction of the Vaccine	500
(b) Potency of tetanus fraction	300
(c) Potency of diphtheria fraction	200
III. Cosmetics	*100 to 300
IV. Rubber condoms	250
V. Homoeopathic medicines .	
(i) Identification test for raw material of botanical origin (other than assay of constituents)	50
(ii) Identification test for raw materials of chemical origin (other than assay)	25
(iii) Limit test for drugs of chemical origin	75
(iv) Assay of total alkaloids or of drugs of chemical origin	30
(v) Identification test for drugs of animal origin or micro-biological .	25
(vi) Fee for testing of mother tinctures, lower potencies up to 3X or equivalent	50

*The exact amount of fee shall be determined by the Director or the Government Analyst, as the case may be.

- NOTE.—**1. For tests not listed in the Schedule, charges will be determined by the Director or the Government Analyst of the laboratory/institute as the case may be.
2. For the tests relating to Ayurvedic, Unani and Siddha medicines, charges will be determined by the Adviser (Indigenous System of Medicine) Director or Govt. Analyst of the Laboratory/Institute as the case may be.

***SCHEDULE C**

(See Rules 23, 61 and 76 and Part X)

Biological and Special Products

- | | |
|---|---|
| 1. Sera | (iv) Oxytetracycline. |
| 2. Solution of serum proteins intended for injection. | (v) Chloramphenicol. |
| †3. Vaccines for parenteral injections. | (vi) Viomycin. |
| 4. Toxins. | (vii) Neomycin. |
| 5. Antigen. | (viii) Bacitracin. |
| 6. Antitoxins. | (ix) Tetracycline. |
| 7. Neo-arsphenamine and analogous substances used for the specific treatment of infective diseases. | (x) Carbomycin. |
| 8. Insulin. | (xi) Erythromycin. |
| 9. Pituitary (Posterior Lobe) Extract. | (xii) Vancomycin. |
| 10. Adrenaline and Solutions of Salts of Adrenaline. | (xiii) Polymyxin B. |
| †11. Drugs and preparations thereof in a form to be administered parenterally— | <p>**12. Any other preparation which is meant for parenteral administration as such or after being made up with a solvent or medium or any other sterile product and which—</p> <p>(a) requires to be stored in a refrigerator; or</p> <p>(b) does not require to be stored in a refrigerator.</p> |
| (i) Penicillin. | 13. Sterilized surgical ligature and sterilized surgical suture. |
| (ii) Streptomycin. | †14. Bacteriophages. |
| (iii) Chlorotetracycline. | |

*Amended by Government of India Notification No. F. 1-30/47-A, dated 5-1-1950.

†Amended by Government of India Notification No. F. 1-8/60-D, dated 31-8-1960.

**Amended by Government of India Notification No. F. 1-14/68-D, dated 26-10-1968.

‡SCHEDULE C(I)

[See Rules 23, 61 and 76]

Other Special Products

1. Drugs belonging to the Digitalis group and preparations containing drugs belonging to the Digitalis group not in a form to be administered parenterally.
2. Ergot and preparations containing Ergot not in a form to be administered parenterally.
3. Adrenaline and preparations containing Adrenaline not in a form to be administered parenterally.
4. Fish Liver Oil and preparations containing Fish Liver Oil.
5. Vitamins and preparations containing any vitamins not in a form to be administered parenterally.
6. Liver extract and preparations containing liver extract not in a form to be administered parenterally.
7. Hormones and preparations containing Hormones not in a form to be administered parenterally.
8. Vaccine not in a form to be administered parenterally.
9. Following drugs and preparations containing them not in a form to be administered parenterally :—
 - (1) Penicillin.
 - (2) Streptomycin.
 - (3) Chlortetracycline.
 - (4) Oxytetracycline.
 - (5) Chloramphenicol.
 - (6) Neomycin.
 - (7) Carbomycin.
 - (8) Erythromycin.
 - (9) Bacitracin.
 - (10) Tetracycline.
 - (11) Gramicidin.
 - (12) Tyrothricin.
 - (13) Viomycin.
 - (14) Framycetin.
 - (15) Griseofulvin.
 - (16) Novobiocin.
 - (17) Nystatin.
 - (18) Oleandomycin.
 - (19) Polymyxin B.
 - (20) Spiramycin.
 - (21) Vancomycin.

‡Amended under Government of India Notification No. F. 1-22/59-D, dated 9-4-1960

SCHEDULE D

[See Rule 43]

<i>Class of drugs</i>	<i>Extent and conditions of exemption</i>
1. Substances not intended for medical use	All provisions of Chapter III of the Act and Rules thereunder subject to the condition that if the substance is imported in bulk, the importer shall certify that the substance is imported for non-medicinal uses, and if imported otherwise than in bulk, each container shall bear a label indicating that the substance is not intended for medicinal use or is intended for some purposes other than medicinal use or is of commercial quality.
@2.	
@3.	
*4. Substances included in Schedule C(I) required for manufacturing purposes which are not intended for medical use in form in which they are imported or which may be notified in the Official Gazette from time to time.	The provisions of Chapter III of the Act and Rules thereunder which require them to be covered by import licences, subject to the condition that the exemption will be confined to holders of licence in Form 28.
†5. The following substances, which are used both as articles of food as well as drugs :—	All the provisions of Chapter III of the Act and Rules thereunder.
(i) All condensed or powdered milk whether pure, skimmed or malted, fortified with vitamins and minerals.	
(ii) Farex, Oats, lactose and all other similar cereal preparations whether fortified with vitamins or otherwise excepting those for parenteral use.	
(iii) Virol, Bovril, Chicken essence and all other similar predigested foods.	
** (iv) Ginger, Pepper, Cumin, Cinnamon and all other similar spices and condiments unless they are specifically labelled as conforming to the standards in the Indian Pharmacopoeia or the official Pharmacopoeias and the official compendia of drug standards prescribed under the Act and Rules made thereunder.	

@Omitted by Govt. of India, Ministry of Health, F.P., W.H. and U.D. Notification No. F. 1-6/62-D, dated 2-7-1969.

†Amended under Government of India Notification No. F. 1-53/55-D, dated 7-1-1957.

*Added under Government of India Notification No. F. 1-7/48-D, dated 10-11-49.

**Amended by G.S.R. No. 19 dated 7-1-1978..... (Govt. of India Notification No. X. 11013/1/77-D & MS, dated 15-12-1977).

**SCHEDULE E

List of Poisonous substances (See Rules 65 and 97)

Name of Poisonous substance	Percentage of poison content below which the substance or its preparation is exempted from the provisions of Rule 65 (4)	Substance or its preparation exempted from all provisions applicable to Schedule E
1	2	3
Acetanilide; alkyl acetanilides
*Acetylmethadol; its salts
Aconite, roots of
Alkaloids, the following; their salts, their esters, salts or their esters, their quaternary compounds
*Acetyldihydrocodeine
*Acetyldihydrocodeinone
Aconite, alkaloids of	0.2	..
Apomorphine	0.20	..
Atropine	0.15	..
Belladonna, alkaloids of	0.15 calculated as hyoscyamine.	..
*Benzylmorphine
*Benzoylmorphine
Brucine	0.20	..
Calabar Beans, alkaloids of
*Coca, alkaloids of	0.10	..
*Cocaine	0.10	..
*Codeine	1.0	..
Colchicum	0.50 calculated as colchicine.	..
Coniine	0.10	..
Cotarnine	0.20	..
Curare, alkaloids of; curare bases
*Diacetylmorphine
*Dihydrocodeine
*Dihydrocodeinone
*Dihydrohydroxycodeinone
*Dihydromorphine
*Dihydroxydihydromorphinone	0.10	..
*Ecgonine
Emetine	1.00	Extracts and tinctures of Ipecacuanha and substances containing less than 0.25 per cent of emetine.
Ephedra, alkaloids of	1.00	..
Ergot, alkaloids of
*Ethylmorphine	0.20	..
Gelsemium, alkaloids of	0.10	..

**Amended by Government of India Notification No. F. 1-63/61-D, dated 17th July,

1	2	3
Homopatropine	0·15	..
Hyoscine	0·15	..
Hyoscyamine	0·15	..
Jaborandi, alkaloids of	0·50	..
Lobelia, alkaloids of	0·50	Cigarettes and smoking mixture containing alkaloids of lobelia.
*Morphine	0·20	calculated as anhydrous morphine.
Nicotine	0·20	..
Papaverine	1·00	..
Pomegranate, alkaloids of	0·50	..
Quebracho, alkaloids of, other than alkaloids of red quebracho
Rauvolfia, alkaloids of
Sabadilla, alkaloids of
Solanaceous alkaloids not otherwise specified in this list	0·15	Calculated as hyoscyamine Cigarettes and smoking mixture containing stramonium.
Stavsaere, alkaloids of	0·20	..
Strychnine.	0·20	..
*Thebaine
Tropacocaine (Benzoylpseudotropine)		
Veratrum, alkaloids of	1·00	..
Yohimba, alkaloids of
Allylisopropylacetylurea
*N-Allylmorphine and any other pentavalent morphine derivative
*Allylprodine; its salts
*Alpha-acetylmethadol; its salts
*Alpha-methadol; its salts
*Alphaprodine; its salts
Amidopyrine; its salts; amidopyrine sulphonates; their derivatives, their salts
Amino-alcohols esterified with benzoic acid, phenylacetic acid, phenylpropionic acid or the derivatives of these acids; their salts	10·00	of esterified amino-alcohols ..
Aminopterin
Ammonia	Smelling salts
Amylnitrite
*Anileridine; its salts

1	2	3
Antimony, oxides of antimony; sulphides of antimony; organic compounds of antimony	Equivalent of 1·00 per cent of antimony trioxide.	..
Apiol
Arsenic; halides of arsenic; oxides of arsenic, arsenates, arsenites, organic compounds of arsenic	Equivalent of 0·01 per cent of arsenic trioxide.	..
Barbituric acid, its salts; derivatives of barbituric acid, their salts; compounds of barbituric acid, its salts, its derivatives, their salts with any other substance
Barium Chloride
*Barium Sulphide
*Benzethidine; its salts
*Beta-acetylmethadol; its salts
Beta aminopropylbenzene (Amphetamine); its salts; its N-alkyl derivatives, their salts; beta aminoisopropylbenzene; its salts; its N-alkyl derivatives, their salts
*Beta-meprodine; its salts
*Beta-methadol; its salts
*Beta-prodine; its salts
Busulphan (1 : 4 dimethanesulphonybutane); its salts
Butyl chloral hydrate
*Cannabis (Indian Hemp); Cannabis resin; galenical preparations of Cannabis; extracts and tinctures of Cannabis; cannabin tannate
Cantharidine; cantharidates	0·10 of cantharidin	..
Carbachol
*4-Carbmethoxy-1, 3-dimethyl-4-phenyl hexamethyleneimine; its salts
*4-Carbmethoxy-1, 2-dimethyl-4-phenyl hexamethyleneimine; its salts
Carbutamide
Chloral formamide
Chloral hydrate
Chlorambucil; its salts
Chloroform	Substances containing less than 10 per cent of chloroform.
Chlorpropamide; its salts
*Clonitazene 2-(P-Chlorobenzyl)-1 diethylaminoethyl - 5 - nitrobenzimidazole); its salts
Creosote from wood	Substances containing 50 per cent of creosote from wood.
Croton oil and seeds of

1	2	3
Cyclophosphamide; its salts
Datura, herb and seeds, preparations of datura	0·15 calculated as hyoscyamine	..
*Desomorphine; its salts	1·50	..
Dextromethorphan; its salts	1·50	..
*Dextromoramide; its salts
Dextrophan; its salts
*Diacetyl-N-allylmorphine; its salts
Diaminodiphenyl Sulphone; its salts and derivatives
Digitalis, glycosides of; other active principles of digitalis	1 unit of activity as defined in the Indian Pharmacopoeia in two grams of the substance.	..
Di-isopropyl flourophosphonate
*Dimenaxadol; its salts
*Dimethylthiambutene; its salts
Dinitrocresols; their compounds with a metal or a base
Dinitronaphthols; dinitrophenols; dinitrothymols
*Dioxaphetyl butyrate; its salts
*Diphenoxylate; its salts
*Diphenylmorpholinopheptanone; its salts
*Dipipanone; its salts
Disodium Stilboestrol diphosphate
Disulfiram
Dithienylamines; dithienylalkylamines
Elaterin
Epinephrine; its salts
Ergot (the sclerotia of any species of Calviceps); extract of ergot; tincture of ergot
Erythrityl tetranitrate
Ethosuximide
*Ethylmethylthiambutene; its salts
*Etoxidine, its salts
Formaldehyde
Formic acid
*Furethidine; its salts
Gallamine; its salts; its quaternary compounds
Glyceryl trinitrate (Nitroglycerine)
Guanidines, the following; Polymethylene diguanidines; di-para-anisyl phenetyl guanidine

Substances containing less than 5 per cent of Formaldehyde.

1	2	3
H/ dantoin, its salts; its derivatives; their salts
Hydrochloric acid	Substances containing less than nine per cent of hydrochloric acid.
Hydrocyanic acid	0·15	..
*Hydromorphanol; its salts
12-Hydroxy-5, 9-dimethyl-2-(2-phen- ylethyl) 6-7-benzomorphan; its salts
*Hydroxypethidine (Bemidone); its salts
Insulin
*Isopropylester of 1-methyl-4-phenyl- 4-carboxylic acid (Phroperidine); its salts
Retobemidone; its salts
Laudeaxium; its salts
Lead acetates; compounds of lead with acids from fixed oils
Leverternol; its salts
*Levo-3-hydroxyl-N-propargylmorphinan; salts
*Levomethrophan; its salts
*Levophenacylmorphan; its salts
*Levomoramide; its salts
*Levorphanol; its salts
Mannomustin; its salts
Mannityl hexanitrate
6-mercaptopurine; its salts
Mercury
Mercuric Chloride; mercuric ammo- nium chloride	1·00 of mercuric chloride.	..
Mercuric iodide	2·00	..
Mercuric nitrate	Equivalent of 3·00 per cent of Mercury (Hg.)	..
Mercury, Organic compounds of	Equivalent of 0·20 per cent of Mercury (Hg.).	..
Mercury, Oxides of
Mercury, Oxycyanides of
Mercuric Potassium iodide	Equivalent of 1·00 per cent of mer- cury (Hg.).	..
Metamizole
*Metazocine; its salts
Metformin; its salts
*Methadone (Amidone); its salts
Methanol
Methotrexate; its salts
Metsuximide
*Methyldesorphine; its salts

1	2	3
*Methyl dihydromorphine; its salts
Methyl phenidate; its salts
*1-methyl-4-phenylpiperidine-4-carboxylic acid, esters of; their salts
*Metapon (Methyldihydromorphine); its salts
*N(2-Methyl-phenethylamino) propyl propionanilide, its salts
*Morpheridine; its salts
*Morphine-N-Oxide; its derivatives; their salts
Mustine; its salts
Nalorphine; its salts
Nitric acid	Substances containing less than nine per cent of nitric acid.
Nitrobenzene
Nitrophenols, ortho meta or para
*Norcodeine; its salts
*Norlevorphanol; its salts
*Normethadanel; its salts
*Normorphine; its salts
Nux vomica; seeds of, preparation of nux vomica	0.20 calculated as strychnine	
*Opium	0.20 calculated as anhydrous morphine	
Orthocaine; its salts
Ouabain
Oxazolidine, its derivatives
Oxychinchoninic acid, derivatives of; their salts; their esters
*Oxymorphone; its salts
Para-aminobenzene sulphonamide; its salts, derivatives of para amino benzene sulphonamide having any of the hydrogen atoms of the para-amino group or of the sulphonamide group substituted by another radical; their salts	Substances intended for topical or external use.
Para-aminobenzoic acid; its salts; its esters, their salts
Paramethadione
*Phenampromide; its salts
Phenformin; its salts
Phenols (any member of the series of phenols of which the first member is phenol and of which the molecular composition varies from member to member by one atom of carbon and two atoms of hydrogen); halogen derivatives of phenols; compounds of phenol with a metal	(i) Substances containing less than one per cent of Phenol.

1	2	3
		(ii) Nasal Sprays mouth washes, pas- tilles, Lozenges capsules, pessaries, ointments, or sup- positories con- taining less than 2.50 per cent of phenol.
*Phenomorphane; its salts
*Phenoperidine; its salts
Phensuximide
Phenylacetylurea
Phenylbutazone; its salts; its deriva- tives; their salts
Phenylcinchoninic acid, its salts, its esters, the salts of its esters
Phenyl-(p-tolymethoxy)-ethylmethyla- mine; its salts
Pholcodine; its salts	1.50	..
Phosphorus yellow
Picric acid	Substances containing less than nine per cent of picric acid.
Picrotoxin
*Piminodine; its salts
3-Piperidino-1-phenyl bicycloheptenyl propanol
Potassium Fluoride	Substances containing less than 1 per cent of Potassium fluo- ride.
Potassium Hydroxide
Procaine, salts of	Combination of Pro- caine with antibio- tics.
*Proheptazine; its salts
*Propoxyphene; its salts
*Racemethorphan; its salts
*Racemoramide; its salts
*Racemoraphan; its salts
Reserpine; its salts; its derivatives; their salts
Salicylcin chroninic acid; its salts; its esters; the salts of its esters
Savin, oil of
Sodium Fluoride	Substances containing less than 1 per cent of sodium fluoride.
Sodium hydroxide	Substances containing less than twelve per cent of sodium hy- droxide.
Sodium nitrite
Strophanthus, Glycosides of strop- phanthus
Sulphonals; alkylsulphonals

1	2	3
Sulphuric acid	Substances containing less than nine per cent of Sulphuric acid.
Thallium, salts of
Thiocarbamide
Thyroid gland, the active principles of; their salts
Tolbutamide
Tribromethyl alcohol
Tri(2-chlorethyl) amine; its salts
Triethanamelamine; its salts
Triethylenethiophosphoramide
*Trimaperidine; its salts
Tropine diphenylmethyl esters; their salts
Troxidone
Zinc phosphide

NOTE.—1. Preparations containing the above substances are also covered by this Schedule unless otherwise specified.

2. The inclusion of any substance in Schedule E does not imply or convey that such substance is exempted from the provisions of rule 30A of the Drugs and Cosmetics Rules.

*Drugs coming within the purview of the Dangerous Drugs Act, 1930.

*SCHEDULE E(I)

(See Rule 161(2))

List of poisonous substances under the Ayurvedic (including Siddha) and Unani Systems of Medicine

A. AYURVEDIC SYSTEM

I. Drugs of vegetable origin

Ahipena	<i>Papaver somniferum</i> Linn.
Arka	<i>Calotropis gigantea</i> (Linn.) R. Br.ex.Ait.
Bhallataka	<i>Semecarpus anacardium</i> Linn.f
Bhanga	<i>Cannabis sativa</i> Linn.
Danti	<i>Baliospermum montanum</i> Mull. Arg.
Dhattura	<i>Datura metel</i> Linn.
Gunj	<i>Abrus precatorius</i> Linn.
Jaipala (Jayapala)	<i>Croton tiglium</i> Linn.
Karaveera	<i>Rerium indicum</i> Mill.
Langali	<i>Gloriosa superba</i> Linn.
Parasika Yavani	<i>Hyoscyamus inibar</i> Linn.
Snuhi	<i>Euphorbia nerifolia</i> Linn.
Vatsanabha	<i>Acontium chasmanthum</i> Stapfex Holm.
Vishamushti	<i>Strychnox nuxvomica</i> Linn.
Shringivisha	<i>Aconitum chasmanthum</i> Stapfex Holm.

*Added under Govt. of India, Ministry of Health, F.P., W.H. & U.D. Notification No. 1-23/67-D dated 2-2-1970.

II. *Drugs of Animal Origin*

Sarpa Visha	Snake poison.
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III. *Drugs of Mineral Origin*

Gauripashana	Arsenic
Hartala	Arseno sulphide
Manahashila	Arseno sulphide
Parada	Mercury.
Rasa Karpura	Hydrargyri subchloridum
Tuttha	Copper sulphate
Hingula	Cinnabar
Sindura	Red oxide of lead
Girisindura	Red oxide of mercury.

B. SIDDHA SYSTEM

Abini	<i>Papaver somniferum</i> Linn.
Alari	<i>Nerium indicum</i> Mill.
Azhavanam	<i>Lawsonia inermis</i> Linn.
Attru thummatti	<i>Citrullis colocynthis</i> Scharad.
Anai Kunri	<i>Adananthera pavonina</i> Linn.
Rattha polam	<i>Aloe barbadensis</i> Mill.
Ilaikalli	<i>Euphorbia neriifolia</i> Linn.
Eezhaththalari	<i>Plumeria acuminata</i> Ait.
Gomatthai	<i>Datura stramonium</i> Linn.
Etti	<i>Strychnos nuxvomica</i> Linn.
Ganja	<i>Cannabis sativa</i> Linn.
Kalappaik Kizhangu	<i>Gloriosa superba</i> Linn.
Kodikkalli	<i>Euphorbia tirugalli</i> Linn.
Chadurakkalli	<i>Euphorbia antiquorum</i> Linn.
Karia polam	<i>Aloe</i> sp.
Kattamanakku	<i>Jatropha glandulifera</i> Roxb.
Kattu thumatti	<i>Cucumis trigonus</i> Roxb.
Kunri	<i>Abrus precatorius</i> Linn.
Cheran Kottai	<i>Semicarpus anacardium</i> Linn.
Thillai	<i>Exoecaria agallocha</i> Linn.
Nabi	<i>Aconitum ferox</i> Wall.
Nervalam	<i>Croton tiglium</i> Linn.
Pugai Elai	<i>Nicotiana tobacum</i> Linn.
Marukkarai	<i>Randia dumetorum</i> Lam.
Mansevikkalli	<i>Euphorbia</i> sp.

C. UNANI SYSTEM

I. *Drugs of vegetable origin*

Afiyun	<i>Papaver somniferum</i> Linn.
Bazrul-banj	<i>Hyoseyamus niger</i> Linn.
Bish	<i>Aconitum chasmanthum</i> Stapfex Holmes
Bhang	<i>Cannabis sativa</i> Linn.
Charas	<i>Cannabis sativa</i> Linn.
Dhatura seeds	<i>Datura metel</i> Linn. (seeds)
Kuchla	<i>Strychnos nuxvomica</i> Linn.
Shokran	<i>Conium maculatum</i> Linn.

II. *Drugs of Animal origin*

Sanp (head)	Snake (head)
Telni makkhi	<i>Mylabris cichori</i> Linn.
						<i>Malabris pustulata</i> Thunb
						<i>Mylabris macilenta</i>

III. *Drugs of Mineral origin*

Darchikna	Hydrargyri perchloridum
Hira	Diamond.
Ras Kapoor	Hydrargyri Subchloridum (calomel)
Shingruf	Hydrargyri bisulphuratum
Zangar	Cupri subacetate
Sammul-Far (Abyaz, Asfar, Aswad and Ahmar)						Arsenic (white, yellow, black and red)
Tootiya	Copper Sulphate
Para	Hydrargyrum
Hartal	Arsenic trisulphide (yellow).

SCHEDULE F

[See Rule 78 and Part X]

PART I—VACCINES

(A) PROVISIONS APPLICABLE TO THE PRODUCTION OF BACTERIAL VACCINES

1. *Definition*—(1) This Part of this Schedule applies to bacterial vaccines made from any micro-organism pathogenic to man or other animal and to vaccines made from other micro-organisms which have any antigenic value.

(2) For the purposes of this Part of this Schedule a bacterial vaccine means a sterile suspension of a killed culture of the micro-organism from which the vaccine derives its name or a sterile extract or derivative of a micro-organism which has been prepared from a genuine culture of the micro-organism.

2. *Staff of Establishment*—The establishment where vaccines are prepared must be under the complete direction and control of a competent expert in bacteriology, who must be assisted by a staff adequate for carrying out the tests required during the preparation of the vaccines and in connection with the finished products.

3. *Proper Name*—The proper name of any vaccine shall be the name of the micro-organism from which it is made, followed by the word "vaccine" unless this Schedule otherwise provides or, if there is no special provision in this Schedule, some other name is approved by the Licensing Authority : Provided that in the case of the undermentioned preparations the proper name of the vaccine may be as follows :

Anti-cholera vaccine;
Anti-typhoid vaccine;

Anti-plague vaccine;
Anti-dysentery vaccine;
Whooping cough vaccine;
Anti-typhoid-paratyphoid (T.A.B.) Vaccine;
Anti-typhoid-paratyphoid (A.B.&C.) Vaccine;
Anti-typhoid-paratyphoid (A&B) and Cholera Vaccine.

4. *Records*—Cultures used in the preparation of vaccine must, before being manipulated into a vaccine, be thoroughly tested for micro-organism. The permanent records which the licensee is required to keep shall include a record of the origin, properties and characteristics of the cultures.

5. *Combined Vaccines*—Vaccines may be issued either singly or combined in any proportion in the same container. In the case of combinations of vaccines a name for the combined vaccine may be submitted by the licensee to the Licensing Authority, and if approved may be used as the proper name of the vaccine.

6. *Labelling*—(1) The label on the container shall indicate the composition of the vaccine by reference either :—

- (a) to the number of micro-organisms per c.c., or
- (b) to the weight of dried substance of micro-organisms per c.c., or
- (c) to the number of micro-organisms or weight of dried substance of micro-organisms used in preparing 1 c.c. of the finished product.

In the case of a combined vaccine the reference to the number of micro-organisms per c.c. or to the weight of dried substance of micro-organism shall distinguish between the several kinds of contributing micro-organisms.

(2) If the vaccine as issued for sale is combined with any substance other than a simple diluent, the exact nature and strength of such substance must be stated on the label.

*(3) In the case of Anti-typhoid-paratyphoid (T.A.B.) vaccine and cholera vaccine, the date of expiry of potency of the vaccine shall be indicated on the label on the container and on every other package or carton in which that container is packed. The date of expiry of potency of any such vaccine shall not be a date which is more than eighteen months after the date on which the vaccine was manufactured.

7. *Tests*—In the case of any vaccine prepared from a micro-organism which does not grow readily in ordinary culture media each batch of the vaccine shall, in addition to being submitted to the general tests for sterility prescribed in the Rules under the Act, be tested either in a similar manner on media which are specially favourable to the growth of the particular micro-organism from which the vaccine was prepared or by injection into an animal of a species known to be susceptible to infection by the particular organism, and no material from any batch shall be issued unless the batch has passed one of these tests.

*Added under Government of India Notification No. F. 18-17/51-DS., dated 7th September, 1953.

**** (B) PROVISIONS APPLICABLE TO VACCINUM VARIOLAE
(SMALLPOX VACCINE)****DEFINITIONS**

1. *International name and proper name* :—The International name of the preparation shall be 'Vaccinum Variolae' and the proper name shall be "Smallpox Vaccine."

2. *Descriptive definition* :—Vaccinum Variolae (Smallpox Vaccine) is a dried preparation of Vaccinia Virus grown in the skin of living animals or in the membranes of the chick embryo or in the vibro cultures of suitable tissues. The preparation shall satisfy all the requirements formulated below.

3. *International standard and reference preparation* :—The International Reference Preparation of Smallpox Vaccine (Established in 1962) is dispensed in ampoules containing 14 mg. of freeze-dried smallpox vaccine. This reference preparation is in the custody of the International Laboratory for Biological Standards, States Serum Institute, Copenhagen. The International Reference Preparation is intended for the calibration of reference preparation for use in this country in the manufacture and laboratory control of Smallpox Vaccine.

4. Terminology

(1) *Primary seed lot* means a quantity of virus adapted to, and grown on the skin of a living animal, which has been processed together and has a uniform composition.

(2) *Secondary seed lot* means a quantity of virus grown in the skin of living animals or in the chorioallantoic membranes of chick embryos or in tissue cultures, which is uniform with respect to composition and is not more than 5 passage removed from a primary seed lot.

(3) *Single harvest* means a quantity of material harvested from one animal or a quantity of material harvested from a group of chick embryos or tissue cultures inoculated, incubated and harvested together.

(4) *Bulk material* means the material at any stage harvesting and before filling into final containers. Bulk material may be prepared from one or a number of single harvests.

(5) *Final Bulk* means a quantity of vaccine after completion of preparations for filling and present on the container from which the final containers are filled.

(6) *Filling lot (final lot)* means a collection of sealed final containers that are homogeneous with respect to the risk of contamination during filling or drying. A filling lot shall, therefore, have been filled in one working session and have been dried together.

(7) *Pock-forming unit* means the smallest quantity of virus suspension that will produce a single pock on the chick chorioallantoic membrane.

(8) *Plaque-Forming Unit (PFU)* means the smallest quantity of virus suspension that will produce a single primary plaque in monolayer cell cultures.

5. *General Manufacturing Requirements*

Subject to the other provisions of the rules the manufacturer of smallpox Vaccine shall maintain the staff, premises and equipment as laid down in Schedule M and shall also comply with the provisions contained in part I(A) of this Schedule in so far as it is applicable to the manufacture of Smallpox Vaccine.

6. *Production Control*

(A) *Control of Source materials Virus Strains*

- (1) The strains of virus used in the production of all seed lots shall be identified by historical records. They shall have been shown to the satisfaction of the Licensing Authority to yield immunogenic vaccines which produce typical vaccinal lesions in the skin of man followed by insusceptibility to subsequent challenge by revaccination with a strain of virus known to protect man against variola. The strain shall produce a characteristic vesticular eruption in the skin of rabbits and reproducible characteristic pock lesions in the chorioallantoic membrane of chick embryos. In addition, the vaccine strains shall be characterized by serological tests and animal inoculation.
- (2) Records shall be maintained of all tests made periodically for verification of strain character.
- (3) The strain used for vaccine production should be one that has never shown a greater tendency to produce generalised lesions or lesions of the nervous system in either man or animals than other strains of vaccinia virus which have been found to be satisfactory without producing severe local lesions and marked systemic disturbance. Strains of so-called 'neurovaccine' shall be excluded.

7. *Animals or tissues for the production of seed virus and vaccine*

(1) Only healthy animals or tissues from healthy animals, susceptible to ectodermal inoculations with vaccinia virus, or chick embryos obtained from healthy flocks shall be used for vaccine production. They shall conform to all the requirements given Para in 10 of these standards. If cell cultures are used for vaccine production they shall be shown to be free from detectable adventitious agents.

(2) Different species of animals may be used for vaccine production or for preparing seed virus. Calves, sheep, buffaloes, donkeys and rabbits may be used successfully.

(3) The chorioallantoic membrane of the developing chick embryo and tissues from the embryos or young animals of susceptible species may also be suitable for virus propagation.

8. *Seed lot System*

A primary seed lot shall be used as original materials for the preparation of Secondary seed lot. The Secondary seed lot shall be not more than five passages removed from a primary seed lot.

If vaccine is produced in the skin of a living animal the Secondary seed lot shall be prepared from the Primary seed lot without passage in chick

embryos or tissues cultures. Vaccine shall be prepared from a seed lot without intervening passage.

(2) Seed lots should be maintained either in dried, frozen or glycerinated forms. If a glycerinated seed lot is used it shall be kept continuously at a temperature below 0°C.

9. *Test on seed lots for the presence of extraneous micro-organisms*

(1) The seed lot in the dilution used as inoculum for the production of vaccine in the skin of animals, shall satisfy the requirements of para 14 of these standards.

(2) The seed lot used for the production of vaccine in chick embryos or in tissue cultures shall after rehydration if applicable, satisfy the requirements of para 14 of these standards.

10. *Production precautions*

The precautions to be taken in the production of smallpox vaccine in matters relating to cleanliness of the premises, rooms, apparatus, equipments and materials, and the precautions against contamination shall be such as to ensure the purity, sterility and strength of the Vaccine and shall be approved by the Licensing Authority, with the following additional precautions, namely :—

(1) *Where Vaccines Produced in the Skin of Living Animals*

(a) The animals shall be freed of ectoparasites, and each animal shall be kept in quarantine under veterinary supervision for at least two weeks prior to the inoculation of the seed virus. Before inoculation the animals shall be cleared and thereafter kept in scrupulously clean stalls until the vaccinal material is harvested.

(b) During a period of five days before inoculation and during incubation the animals shall remain under veterinary supervision. They shall remain free from any sign of disease, and daily rectal temperature shall be recorded. If any abnormal rise in temperature occurs, or if any clinical sign of disease is observed the production of vaccine from the group of animals concerned shall be suspended until the cause of these irregularities has been resolved. The prophylactic and diagnostic procedures adopted to exclude the presence of infectious disease shall be submitted for approval, to the Licensing Authority.

(c) The inoculation of seed virus shall be made on such parts of the animal as are not liable to be soiled by urine and faeces. The surface used for inoculation shall be so shaved and cleaned as to procure the nearest possible approach to surgical asepsis. If any antiseptic substance deleterious to the virus is used in the cleaning process it shall be removed by thorough rinsing with sterile water prior to inoculation. During inoculation the exposed surface of the animal not used for inoculation shall be covered with sterile covering.

(d) Before the collection of the vaccinal material, any antibiotic shall be removed and the inoculated area shall be subjected to a repetition of the cleaning process. The uninoculated surfaces shall be covered with sterile covering.

(e) Before harvesting, the animal shall be killed painlessly. The animals shall be exsanguinated before harvesting to avoid heavy admixture of the vaccinal material with blood.

(f) The vaccinal material from each animal shall be collected separately with aseptic precautions.

(g) All animals used in the production of vaccine after being killed shall be examined by autophagy. If evidence of any generalised or systemic disease other than vaccinia is found, the vaccinal material from that animal shall be discarded. If the disease is considered to be a communicable one, the harvest from the entire group of animals exposed shall be discarded.

(2) *Where Vaccines Produced in the chick embryo :—*

- (a) Only eggs from flocks known to be free from disease, including avian leucosis, shall be used.
- (b) In particular, it is desirable that the eggs should be derived from flocks free from salmonella pullorum, Mycobacterium tuberculosis, Rous virus, mycoplasma and other agents pathogenic for chickens.
- (c) Living embryos after incubation for a suitable period shall be inoculated with seed virus which shall satisfy the requirements of paras 8 and 9 of these standards. After further incubation for a suitable period, the vaccinal material shall be harvested with aseptic precautions.

(3) *Where Vaccines produced in tissue culture :—*

- (a) only primary tissue cultures from animals known to be free from disease shall be used. The virus shall be drawn and harvested with aseptic precautions. No material of human origin shall be added to the cultures at any stage.
- (b) Suitable antibiotics in minimum concentrations required for sterility may be used but the use of penicillin and streptomycin is prohibited.

11. *Control of the Bulk material*

Initial treatment

(1) The vaccinal material harvested from the skin of each animal shall be subjected to a treatment designed to reduce its contents of living extraneous micro-organisms. If this is necessary, it should satisfy the requirements of para 14. No antibiotic shall be added to the bulk material.

(2) The treatment of the vaccine may consist of the addition of a suitable antibacterial substance or of the removal of micro-organisms by centrifugation.

(3) Vaccinal material collected from chick embryos or tissue cultures does not need such treatment, but glycerol or an antibacterial substance should be added as a precaution against later contamination.

12. *Final bulk*

(1) After the initial treatment the vaccine may be subjected to additional processes before dilution of the bulk material.

(2) Before making up a final bulk, it should be necessary to do preliminary tests on the single harvests for potency and for the presence of living extraneous micro-organisms.

13. *Test for virus concentration on the final bulk*

The final bulk pass the test for virus concentration described in para 24 of these standards.

14. *Tests for the presence of living extraneous micro-organisms in the final bulk prepared in the skin of living animals.*

The final bulk shall pass the following tests for the presence of living extraneous micro-organisms, unless these tests have already been passed by each of the single harvests represented in the final bulk.

15. *Tests for total bacterial content*

(1) Suitable dilutions of L : 10 and L : 100 of the final bulk shall be made in suitable diluent not deleterious to living bacteria. At least 1 ml samples of each dilution shall be cultured on nutrient-broth-agar plates. The plates shall be incubated for 72 hours between 15°C and 22°C and for a further period of 48 hours between 35°C and 37°C. From the number of colonies appearing on the plates the number of living bacteria in 1 ml of the final bulk shall be calculated. If this number exceeds 500, the final bulk shall be subjected to further treatment or be discarded.

(2) Suitable control plates containing higher dilutions of the final bulk shall be included in this test in order to make sure that the number of colonies appearing on the test plates has not been influenced by the inhibitory action of any preservative present in the final bulk.

16. *Test for the presence of Escherichia Coli*

At least three 1 ml samples of 1 : 10 dilution of the final bulk shall be cultured in three McConkey liquid media tubes containing 10 ml of the medium for differentiating *E. Coli* from other bacteria. The tubes shall be incubated for 48 hours at 35° to 37°C. If *E. Coli* is detected, the final bulk shall be subjected to further treatment or be discarded.

17. *Test for the presence of haemolytic streptococci coagulase positive staphylococci, or any other pathogenic micro-organisms which are known to be harmful if introduced into the human body by the process of vaccination*

(1) Undiluted final bulk or vaccine of 0.1 ml each shall be cultured on three blood agar plates and the plates should be incubated at 35°C to 37°C for 2 days. The colonies appearing after incubation shall be examined critically for *B. anthracis* haemolytic streptococci, Coagulase positive *Staphylococci* or any other pathogenic micro-organisms. If any of these organisms are detected they shall be subjected to confirmatory test.

(2) If any of the organisms mentioned are detected, the final bulk shall be subjected to further treatment or be discarded.

18. *Test for the presence of Clostridium tetani and other pathogenic spore-forming anaerobes*

(1) 0.5 ml of undiluted final bulk or vaccine shall be added in flasks containing 50 ml of Robertson's Cooked meat medium, the flasks shall then

be held at 65°C for one hour and then incubated at 35° to 37° for at least one week. At least two flasks shall be used for each test.

(2) In case of any suspected growth, subcultures shall be made on two plates of a suitable medium which shall be incubated anaerobically at the same temperature. All anaerobic colonies shall be examined and identified and if *Cl. tetani* or other pathogenic spore-forming anaerobes are present the final bulk shall be discarded.

(3) Organisms resembling pathogenic clostridia found in the tube culture from which the subculture was made may be tested for pathogenicity by inoculation into animals as follows : Groups of not less than two guinea pigs and five mice are used for each tube culture to be tested. 0.5 ml of the culture is mixed with 0.1 ml of a freshly prepared 4 per cent solution of calcium chloride and injected intramuscularly into each of the guinea-pigs : 0.2 ml of the culture mixed with 0.1 ml of this calcium chloride solution is injected intramuscularly into each of the mice. The animals are observed for one week. If any animal develops symptoms of tetanus, or if any animal dies as a result of infection with spore-forming anaerobes, the final bulk should be discarded.

(4) If other methods are used for this test, they should have been demonstrated to the satisfaction of the Licensing Authority to be at least equally effective for detecting the presence of *Cl. tetani* and other pathogenic spore forming anaerobes.

19. *Test for bacteriological sterility of the final bulk prepared in chick embryos or in tissue cultures.*

Each final bulk shall be tested for bacterial sterility according to the requirements given in the Indian Pharmacopoeia for the time being. If growth appears in any of the cultures the final bulk shall be discarded or the test repeated. The final bulk shall be discarded if the same type of organism appears in more than one test, but final bulk shall be passed unless the final test shows no growth throughout.

FILLING AND CONTAINERS

20. *Filling rooms*

Filling shall be performed in rooms reserved for this purpose. These shall be sterile rooms equipped specifically for transferring measured quantities of finished biological substances from bulk containers to the final containers. Strict dust control measures and aseptic techniques shall be enforced to ensure that the product is not contaminated during the filling process.

21. *Filling procedures*

(1) Filling operations shall be conducted in such a way as to avoid any contamination or alteration of the product. These shall take place in areas that are completely separate from those in which living micro-organisms, including viruses, are handled.

(2) The filling process shall be checked at least twice each year at the end of a working day by filling not less than 500 ampoules with a nutrient medium containing no antibiotics or bacteriostatic substances and incubating the complete batch of filled ampoules. Not more than 1 per cent of the ampoules filled in this way should show signs of contamination and all contaminants should be identified.

(3) All containers of the final vaccine shall be shown to be sterile before filling and shall be made of a material demonstrated, to the satisfaction of the Licensing Authority, to have no deleterious effect on the vaccine.

(4) Containers of dried vaccine shall be hermetically sealed under vacuum or after filling with pure, dry, oxygen-free nitrogen or any other gas not deleterious to the vaccine.

(5) All hermetically sealed containers shall be tested for leaks after sealing. All defective containers shall be discarded.

(6) Single and multiple-dose containers may be used. Each container of dry vaccine should be issued together with an ampoule of sterile reconstituting fluid. This fluid may contain glycerol and/or some suitable antiseptic substance. The containers shall be issued in a form that renders the process of reconstitution as simple as possible.

CONTROL TESTS ON FINAL PRODUCT

22. *Identity test*

(1) An identity test shall be performed one at least on labelled container from each filling lot by appropriate methods.

(2) The test for virus concentration as described in para 24 may serve as an identity test.

(3) A test may also be made in the scarified skin of rabbits. Suitable dilutions of vaccine shall be applied on scarified areas of skin. After four to seven days the vaccine should produce lesions characteristic of vaccinia.

23. *Test for virus concentration on vaccine in final containers*

(1) A test for virus concentration shall be made on each filling lot in accordance with the requirement described in para 24. For this purpose the dried vaccine shall be reconstituted to the form in which it is to be used for human inoculation before the test is made.

(2) Tests shall be done in parallel with a reference vaccine which has been calibrated against the International Reference Preparation of Smallpox Vaccine.

24. *Test for virus concentration in membranes of chick embryos*

At least ten chick embryos, each of about 12 days incubation, shall be divided into two equal groups. To the chorio-allantoic membrane of each embryo of the first group 0.1 ml or 0.2 ml of a suitable dilution of the vaccine shall be applied. To the membrane of each of the second group of embryos 0.1 ml or 0.2 ml of another suitable dilution of the vaccine shall be applied. After the optimal time of incubation the total number of discrete specific lesions shall be counted on the membrane of each embryo. The dilutions shall be so chosen that the membranes of at least one of the groups yield countable numbers of lesions exceeding ten per membrane. From the number of lesions counted in this group and from dilution and columns used, the number of pockforming units in one ml of the undiluted vaccine shall be calculated. This number shall exceed 1×10^8 .

25. *Other tests*

Tests for virus concentration in the scarified skin of rabbits shall also be used provided it has been shown that the results correlate with those obtained using the membranes of chick embryos.

26. *Test for the presence of extraneous living micro-organisms in the vaccine in final containers*

Not less than four final containers (or not less than 10 if single-dose containers) giving a total pooled quantity which is equivalent to a volume of not less than 0.5 ml shall be taken at random from each filling lot in such a manner that all stages of the filling from the bulk container shall be represented. For this purpose the dried vaccine shall be reconstituted to the form in which it is to be used in human inoculation. The vaccine thus collected shall pass the test described in paras 15 and 19 whichever is applicable.

27. *Innocuity test*

Each filling lot shall be tested for abnormal toxicity by appropriate tests involving injection into rabbits. The tests shall be approved by the Licensing Authority. Mice and guinea-pigs may also be used for this test.

28. *Heat-resistance test on dried vaccine*

At least one container of dried vaccine from each filling lot shall be incubated at a temperature of not less than 37°C for not less than 4 weeks and tested for virus concentration. The vaccine passes the test if the requirements described in para 24 are fulfilled and at least one tenth of the virus concentration is retained.

29. *Preservatives and other substances added.*

No antibiotic shall be added to Smallpox Vaccine. If the reconstituted dried vaccine contains preservatives or other added substances such substances shall have been shown, to the satisfaction of the Licensing Authority to have no deleterious effect on the product in the amount present and to cause no untoward reactions in vaccinated subjects. If phenol is present, its concentration shall not exceed 0.5 per cent. Further, the substance used shall fulfil the requirements of the Indian Pharmacopoeia.

MISCELLANEOUS

30. *Records*

Records shall be permanent and clearly indicate all steps in processing, testing, filling and distribution. Written records shall be kept of all tests irrespective of their results. The records shall be maintained in a manner approved by the Licensing Authority. The records shall be retained throughout the period of a lot or a batch of the vaccine has been given a date of expiry and be available at all times for inspection by the Inspector.

31. *Sampling*

Records shall be maintained of the complete passage history of all cultures kept by the manufacturer. The cultures shall be labelled and stored in a safe, orderly manner.

32. (1) *Labelling*

(a) Subject to the other provisions of these rules, the label on the container shall show the following, namely :—

- (i) the name of the vaccine (i.e. the International name or the proper name),

- (ii) the principal place of business of the manufacturer,—
- (iii) the Batch number or the lot number, and
- (iv) the total number of doses in the container.

(b) The label on the package shall, in addition to the information shown on the label of the container, give the following particulars :—

- (i) the name and address of the manufacturer,
- (ii) the manufacturing licence number being preceded by the words "Manufacturing Licence Number" or "Manufacturing Licence No." or "M.L." when the vaccine has been manufactured in this country.
- (iii) the date of manufacture and the date of expiry.
- (iv) the precautions necessary for preserving the properties of the vaccine, and
- (v) if any antiseptic or preservative has been added, the nature and percentage thereof.

(2) The following additional information shall be given in the leaflet accompanying the package, namely :—

- (a) Conditions of storage,
- (b) instructions for use,
- (c) the method of reconstitution of the vaccine, and
- (d) a statement that, after rehydration of the dried vaccine, the vaccine should be used within six hours.

33. *Storage Conditions*

Before being distributed by the manufacturing establishment or before being issued from a depot for the maintenance of reserves of vaccine, all dried vaccines in their final containers shall be kept constantly at a temperature below +10°C.

34. *Expiry Date*

The date after which dried vaccine may not be used shall be not more than 36 months after passing the last test for virus concentration. The expiry date shall not be more than 36 months after passing the last test for virus concentration. The expiry date shall not, however, be more than twelve months for dried vaccine from the date on which the vaccine was issued by the manufacturer.

(C) PROVISIONS APPLICABLE TO THE PRODUCTION OF VACCINES CONTAINING LIVING ORGANISMS, VIRUSES OF OTHER POTENTIALLY INFECTIVE AGENTS OTHER THAN VACCINE LYMPH (VACCINIA)

1. Every substance other than Vaccine Lymph (Vaccinia) containing, or alleged to contain, bacteria, or virus or other potentially infective agent in the living condition shall be tested in such manner as the Licensing

Authority shall approve in each particular case for the purpose of determining—

- (a) that the substance contains in living condition the bacteria, virus or other potentially infective agent which it is alleged to contain;
- (b) that its administration is free from danger;
- (c) that it is free from living organisms other than those which it is alleged to contain.

2. The proper name for such a substance shall be that which the Licensing Authority in each particular case shall approve in writing.

(D) PROVISIONS APPLICABLE TO THE PRODUCTION OF CARBOLISED
ANTI-RABIC VACCINE

1. *Definition and Proper Name*—Carbolised anti-rabic vaccine is a sterile suspension of the brain substance of rabbits or sheep or other suitable animals which have died, or been killed when moribund by the administration of an anaesthetic, or other suitable method, after showing characteristic symptoms following subdural inoculation of rabies fixed virus in the form of a suspension of brain substance of rabbits in which the fixed virus strain has been maintained. The virus in the brain suspension shall have been inactivated by the addition of phenol. Its proper name is "Carbolised Anti-rabic Vaccine".

2. *Strain of fixed Rabies Virus is to be used*—The strain of fixed Rabies Virus to be used in the preparation shall be one approved by the Licensing Authority.

3. *Staff of establishment*—The establishment in which carbolised anti-rabic vaccine is prepared must be under the complete direction and control of a competent expert who must be assisted by a staff adequate for carrying out the test required during the preparation of the vaccine and in connection with the finished product.

4. *Condition and housing of animals*—(1) The animals used in the production of carbolised anti-rabic vaccine must be adequately and healthily housed.

(2) Only healthy animals may be used in the production of carbolised anti-rabic vaccine. Each animal intended to be used as the source of carbolised anti-rabic vaccine must, before being passed for the production of carbolised anti-rabic vaccine, be subjected to a period of observation in quarantine for at least five days. During the period of quarantine the animal must remain free from any sign of disease.

5. *Precautions to be observed in preparation*—(1) A special room, with impervious walls and floor, which can be washed and when necessary, chemically disinfected, must be provided for the inoculation of animals and the removal of brains used in the maintenance of the Fixed Virus Strain and the manufacture of carbolised anti-rabic vaccine.

(2) The inoculation of animals and the removal of their brains must be carried out with full aseptic precautions.

(3) Tests for bacterial sterility of brains of animals used for the maintenance of the Fixed Virus Strain for the preparation of carbolised anti-rabic vaccine must be carried out at the time of their removal and any brain material found to show bacterial contamination must not be employed in the manufacture of the vaccine. The sterility tests to be employed shall be those laid down in Rules 114 to 119.

6. *Records*—The licensee shall maintain permanent records of the origin, properties, and characteristics of the Fixed Rabies Virus Strain and of the serial passages made for its maintenance. Records shall be maintained of each animal passage made for the manufacture of the carbolised anti-rabic vaccine and of the manipulation of the brain material used.

7. *Labelling*—The label on the container shall indicate the percentage for brain substance present in the vaccine.

8. *Issue*—Carbolised Anti-rabic Vaccine shall not be issued earlier than 10 days from the date of addition of phenol to the brain suspension. A test for presence of phenol must be made before issue.

(E) PROVISIONS APPLICABLE TO TETANUS TOXOID

1. *Definition and Proper Name*—Tetanus Toxoid is tetanus toxin (the sterile filtrate from a culture on nutrient broth of *Clostridium Tetani*) the specific toxicity of which has been completely removed by the action of chemical substances in such a manner that it retains efficient properties as an immunizing antigen. Its proper name is "Tetanus Toxoid".

2. *Labelling*—The label on the container shall indicate the dose or doses, appropriate for administration at one injection to a human subject.

3. *Tests*—Tetanus Toxoid shall be submitted to the following tests, and it shall not be issued unless it passes all of the tests :

(a) *Tests for sterility*—Tetanus Toxoid shall be submitted to the tests for sterility as required under Part X of the Rules, and in addition it shall be tested on media and under conditions approved by the Licensing Authority as being specially favourable for the growth of *Clostridium Tetani*.

(b) *Tests to determine that the specific toxicity of the toxin used in its preparation has been completely removed*—5 c.c. of the tetanus toxoid shall be injected into each of not less than five normal guinea-pigs, each weighing from 250 to 350 grammes. If this injection produces any symptom of tetanus in any of the animals injected within 21 days of injection the tetanus toxoid shall be held not to have passed the tests.

(c) *Test for potency as an immunizing antigen*—The tests shall be carried out on not less than nine normal guinea-pigs, each weighing from 250 to 350 grammes. Each guinea-pig shall receive by injection the tetanus toxoid, either in a dose of 5 c.c. on one occasion, or in two doses each of 0.1 c.c. on each of two occasions separated by an interval of not more than four weeks. It shall be permissible to include in the test guinea-pig injected by either of these two methods provided that the total number so included is not less than nine. At a date not later than six weeks after the single injection, hereinbefore prescribed, or if they have received the two injections, hereinbefore prescribed, at a date not later than two weeks after the second injection, the tetanus anti-toxin present in the serum of each guinea-pig shall be determined.

If the serum of each of two-thirds or more of the guinea-pigs tested carried out on not less than nine normal guinea-pigs, each weighing from serum or alternatively, if the serum of each of one-third or more of the guinea-pigs tested contains one international unit or more of tetanus anti-toxin per c.c. of serum the tetanus toxoid shall be accepted as sufficiently potent.

PROVISIONS APPLICABLE TO TETANUS TOXOID PREPARED FOR ISSUE IN FORMS OTHER THAN SIMPLE SOLUTION

4. *Proper Name*—The proper name of any form of tetanus toxoid other than that of simple solution shall be "Tetanus Toxoid" together with a phrase indicating the nature of the additional process to which it has been subjected, e.g., "Tetanus Toxoid, Alum Precipitated" or "Alum Precipitated Tetanus Toxoid".

5. *Labelling*—The label on the container shall indicate the dose, or doses, appropriate for administration at one injection to a human subject.

6. *Tests*—(a) When tetanus toxoid is prepared for administration in forms other than simple solution, such as Alum Precipitated Tetanus Toxoid, the tetanus toxoid from which such forms are prepared shall be submitted to, and shall pass, the tests for sterility and for absence of specific toxicity hereinbefore prescribed.

(b) The product, after precipitation or other process used for its final preparation shall again be subjected to the sterility tests hereinbefore prescribed, with such modifications as the nature of the product may require to make the test effective.

(c) The product, after the precipitation or other process used for its final preparation shall be subjected to the tests for absence of specific toxicity and for potency as an immunizing antigen hereinbefore prescribed, with the modification that the dose injected in the test for absence of specific toxicity and in the test for potency as an immunizing antigen when a single dose is administered, shall be 1 c.c.

PART II—TOXINS AND ANTIGENS

(A) PROVISION APPLICABLE TO THE REAGENTS USED IN THE SCHICK TEST FOR THE DIAGNOSIS OF SUSCEPTIBILITY TO DIPHTHERIA

1. *Definitions and Proper Names*—(1) The reagents used in the Schick test are two, Schick Toxine and Schick Control. Their proper names respectively are 'Schick Test Toxin' and 'Schick Control'.

(2) Schick Test Toxin is a sterile filtrate from a culture on nutrient broth of the specific organism of Diphtheria (*Corynebacterium diphtheriae*). It may be issued either—

(a) undiluted, accompanied by a container in the same box or carton holding such volume of sterile saline solution as, when mixed with the accompanying quantity of the undiluted toxin, will make a dilution of the strength proper for use in the test. The proper name of the substance in this form is "Schick Test Toxin (undiluted)"; or

(b) already diluted with an appropriate saline solution to the strength proper for use in the test. The proper name of the substance in this form is "Schick Test Toxin (diluted for use)".

(3) Schick Control is prepared from the same batch of Schick Toxin as that with which it is used for sale, by destroying the specific toxicity. This is effected by heating the toxin in such a manner as to keep it at a temperature not lower than 70°C. for a time not shorter than five minutes. Schick Control is issued in a dilution not weaker than that in which the corresponding toxin is used in the test.

(4) The dilution of Schick Toxin proper for the test is that in which 0.2 c.c. contains one test dose.

2. *Tests for potency*—The test dose of Schick Toxin for the purpose of the foregoing provision shall be measured by the following tests :—

(a) By intracutaneous injection into normal guinea-pigs in mixtures with different proportions of diphtheria anti-toxin. One test dose mixed with 1/750th or more of a unit of anti-toxin must cause no local reaction but mixed with 1/1,250th or less of a unit of anti-toxin must cause a definite local reaction of the type known as the "Positive Schick Reaction";

(b) by intracutaneous injection into normal guinea-pigs without admixture with anti-toxin. 1/50th of one test dose must not cause, and 1/25th of one test dose must cause, a definite local reaction of the type known as the "Positive Schick Reaction".

3. *Application of Rule 120*—Rule 120 shall apply to Schick Toxin (diluted for use) as being a substance so unstable in solution that the delay occasioned by the completion of the sterility test on filled containers prescribed by the Rules would render its issue in active form impossible.

(B) PROVISIONS APPLICABLE TO DIPHTHERIA PROPHYLACTIC

1. *Definition and Proper Name*—Diphtheria Prophylactic is diphtheria toxin (the sterile filtrate from a culture on nutrient broth of *Corynebacterium diphtheria*), or material derived therefrom the specific toxicity of which has been reduced to a low value either by the action of chemical substances, or by the addition of diphtheria anti-toxin, or by both methods, but, in any case, in such a manner that it retains efficient properties as an immunizing antigen. Its proper name is "Diphtheria Prophylactic".

2. *Labelling*—The label on the container shall bear a statement of the dose (hereinafter referred to as the "human dose") appropriate for administration at one injection to a human subject.

3. *Tests*—Diphtheria Prophylactic shall be submitted to the following tests—

(a) *Tests to determine that the specific toxicity of the toxin used in its preparation has been so reduced that it does not exceed the prescribed maximum*—Five human doses of the Diphtheria Prophylactic under test shall be injected into each of five normal guinea-pigs each weighing 250 to 350 grammes. This injection must not cause the death of any of the guinea-pigs within six days following the injection. If all the guinea-pigs injected survive for six days but any of them dies within thirty days following the injection from the specific toxæmia, one human dose of the Diphtheria Prophylactic under test shall be injected into each of five normal guinea-pigs, each weighing 250 to 350 grammes. This injection must not cause the death of any of the guinea-pigs within thirty days following the injection.

If a batch of Diphtheria Prophylactic is shown by either of these tests to have a greater toxicity than the maximum hereby indicated, it shall not be issued unless and until the toxicity has been so reduced by further treatment that it does not exceed that maximum.

(b) *Test for potency as an immunizing antigen.*—A quantity of Diphtheria Prophylactic not exceeding five human doses shall be injected on one occasion into each of at least ten normal guinea-pigs; or, alternatively, a quantity of Diphtheria Prophylactic not exceeding one-tenth of a human dose shall be injected into each of at least ten normal guinea-pigs on each of two occasions, separated by an interval of not more than four weeks. The guinea-pigs shall be tested for immunity to diphtherial toxin, if they have received the single injection hereinbefore prescribed, at a date not later than six weeks after injection, and if they have received the two injections hereinbefore prescribed, at a date not later than three weeks after the second injection, by intracutaneous injection into each guinea-pig of one test dose of Schick Toxin. If more than two out of ten guinea-pigs thus tested or more than one quarter of the number tested if this is greater than ten, exhibits a positive Schick reaction, the batch of Diphtheria Prophylactic shall be treated as insufficiently potent, and shall not be issued.

Provided that in the case of the forms of Diphtheria Prophylactic known as Toxin-Anti-toxin Floccules and Toxoid-Anti-toxin Floccules the Prophylactic may be similarly injected into nine or more normal guinea-pigs, which may be tested for immunity to Diphtheria Toxin by two separate but simultaneous intracutaneous injections into each of at least nine of these guinea-pigs of one test dose and two test doses, respectively, of Schick Toxin. If two-thirds or more of the guinea-pigs tested do not exhibit a positive reaction to *one* test dose of Schick Toxin; or alternatively, if one-third or more of the guinea-pigs tested do not exhibit a positive reaction to *two* test doses of Schick Toxin, the batch shall be accepted as sufficiently potent.

(C) PROVISIONS APPLICABLE TO TUBERCULINS AND OTHER PREPARATIONS FROM THE *BACILLUS TUBERCULOSIS* AND ITS CULTURES

(NAME—The name “tuberculin” has been frequently applied to any extract, suspension or other preparation of the *Bacillus tuberculosis* or of media on which that bacillus has been cultivated. In the following Part of this Schedule the name is used in a more restricted sense and applies only to tuberculins as therein defined.)

TUBERCULINS

1. *Definition and Proper Name*—(1) Tuberculins are preparations of fluid media on which the *Bacillus tuberculosis* has been grown in artificial culture and which have been freed by filtration from the bacilli.

(2) For the purposes of this Schedule tuberculins are classified in two groups, (a) Old Tuberculin, and (b) Tuberculin, Bouillon Filtrate.

2. *Old Tuberculin*—(1) Old Tuberculin is the concentrated filtrate from the growth of *Bacillus tuberculosis* on a suitable nutrient broth. For its preparation the bacillus must be grown at approximately 37°C. for a period, usually not less than six weeks, sufficient to allow the surface of the fluid medium to become covered by a thick growth of the bacillus. At

the end of this period the fluid medium, from which the bacilli may or may not have been previously separated by filtration, must be concentrated by evaporation to one-tenth of its original volume and then be filtered. If the required test for potency shows that the preparation so concentrated is more potent than the standard preparation, the potency may be reduced to the required degree by appropriate dilution. If the test shows that the potency is less than that of the standard preparation, it shall not be increased by further evaporation. The proper name of the preparation is "Old Tuberculin", with or without a suffix such as T., or P.T. The suffix T., if used, will indicate that the bacillus used in preparing the Tuberculin was obtained from a case of human infection, and the suffix P.T. the bacillus used was obtained from a case of bovine infection.

(2) The standard preparation of Old Tuberculin is a quantity of Old Tuberculin kept in the National Institute for Medical Research, Hampstead.

(3) Each batch of Old Tuberculin shall be tested for potency by observation of its specific toxicity, by a method approved by the Licensing Authority, in such a way that the potency of the preparation under test is measured by comparison with that of the standard preparation. Old Tuberculin shall not be issued if its activity differs from that of the standard preparation to such an extent that the difference is revealed by the test.

(4) Each batch of Old Tuberculin shall be tested for the absence of non-specific toxicity by the subcutaneous injection of 0.5 c.c. into a normal guinea-pig, and shall be treated as having passed the test if such injection does not cause death or serious symptoms.

3. *Tuberculin Bouillon Filtrate*—(1) Tuberculin Bouillon Filtrate is the unconcentrated filtrate from the growth of *Bacillus tuberculosis* on a suitable nutrient broth. For its preparation the bacillus must be grown at approximately 37°C. for a period usually not less than six weeks, sufficient to allow the surface of the fluid medium to become covered by a thick growth of the bacillus. At the end of this period the medium is freed from bacilli by filtration through a bacteria-proof filter. The proper name of the preparation is "Tuberculin Bouillon Filtrate", with or without a suffix such as T.O.A. or P.T.O. The suffix T.O.A. if used, will indicate that the bacillus used in preparing the Tuberculin Bouillon Filtrate was obtained from a case of human infection; and the suffix P.T.O. will indicate that the bacillus used was obtained from a case of bovine infection.

(2) Each batch of Tuberculin Bouillon Filtrate shall be tested for the absence of non-specific toxicity by the subcutaneous injection of 5 c.c. into a normal guinea-pig, and shall be treated as having passed the test if such injection does not cause death or serious symptoms.

4. *Tests for sterility*—All tuberculins shall be tested for sterility in accordance with Rules 115 to 119. Tuberculin Bouillon Filtrate shall be tested in addition for absence of living tubercle bacilli by a method satisfactory to the Licensing Authority.

TUBERCLE VACCINES

5. *Definition and Proper Name*—Tubercle vaccines are preparations made from the bacillary substance obtained by growth of the *Bacillus tuberculosis* on artificial media, and consisting of suspensions of the killed organism or of products therefrom, in water or other suitable suspending

fluids. The proper name is "Tubercle Vaccine", and any other descriptive title or symbol indicating the origin of the bacilli or the nature of the process of preparation must be used in addition to, and not in substitution for, the name "Tubercle Vaccine".

6. *Application of provisions as to bacterial vaccines*—The provisions of Part I(A) of this Schedule (which relate to the production of bacterial vaccines) shall apply to the production of tubercle vaccines.

(D) PROVISION APPLICABLE TO STAPHYLOCOCCUS TOXOID

1. *Definition and Proper Name*—Staphylococcus Toxoid is staphylococcus toxin (the sterile filtrate from a culture on a suitable medium of a toxigenic strain of *staphylococcus*), the specific toxicity of which has been reduced to low value by the action of chemical substances in such a manner that it retains efficient properties as an immunizing antigen. Its proper name is "Staphylococcus Toxoid".

Staphylococcus Toxoid may be issued either—

(a) undiluted; or

(b) already diluted with an appropriate saline solution to the strength suitable for injection.

2. *Labelling*—The label on the container shall indicate the dose, or doses, appropriate for administration at one injection to a human subject.

3. *Tests*—Staphylococcus Toxoid shall be submitted to the following tests, it shall not be issued unless it passes all of the tests.

(a) *Tests to determine that the specific toxicity of the toxin used in its preparation has been sufficiently reduced*—(i) One volume of the undiluted staphylococcus toxoid shall be added to four volumes of physiological saline solution; equal volumes of this dilution of staphylococcus toxoid and of a 2 per cent suspension of washed red blood corpuscles of the rabbit shall be mixed; when the mixture is heated to 37°C. for one hour there must be no significant haemolysis.

(ii) 0.2 c.c. of the undiluted staphylococcus toxoid shall be injected intracutaneously into a normal rabbit or guinea-pig; this injection may cause a slight local reaction but must not produce necrosis.

(iii) Two rabbits shall be injected intravenously with doses of staphylococcus toxoid calculated at the rate of 2.5 c.c. per kilogram body weight; this injection must not cause the death of either rabbit within three days following the injection.

(b) *Tests of non-specific toxicity*—Two normal mice shall be injected intraperitoneally with 0.5 c.c. of the undiluted toxoid; this injection must cause the death of either animal within seven days following the injection.

(c) *Tests for potency as an immunizing antigen*—1 c.c. of the undiluted staphylococcus toxoid shall be injected into each of not less than nine normal guinea-pigs on each of two occasions separated by an interval of not more than four weeks; at a date not later than two weeks after the second injection the serum of each guinea-pig shall be determined.

If the serum of each of two-thirds or more of the guinea-pigs tested contains 0.5 unit or more of staphylococcus anti-toxin per c.c. of serum, or alternatively if the serum of each of one-third or more of the guinea-pigs

tested contains 1 unit or more of staphylococcus anti-toxin per c.c. of serum, the toxoid shall be accepted as sufficiently potent.

PART III—PROVISIONS APPLICABLE TO THE PRODUCTION OF ALL SERA FROM LIVING ANIMALS

1. Condition and housing of animals—(1) The animals used in the production of sera must be adequately and healthily housed.

(2) Only healthy animals may be used in the preparation of sera, and in particular the presence of glanders in horses or other equidae and of tuberculosis in cattle must be excluded by testing with mallein and tuberculin respectively.

(3) Every new animal intended to be used as a source of serum must be subjected to a period of observation in quarantine for at least seven days, before being admitted to the stables in which the serum-yielding animals are housed.

(4) Every animal used as source of serum must either be actively immunized against tetanus toxin or must be passively immunized against that toxin by injections of tetanus anti-toxin in such doses as to ensure the constant presence of that anti-toxin in the blood during the whole period of the use of the animal as a source of serum.

2. Staff of establishment—The establishment must be under the complete direction and control of a competent expert in bacteriology and serology, assisted by a staff adequate for carrying out the tests required during the preparation of the sera and in connection with the finished products.

3. Precautions to be observed in preparation—(1) Laboratories where sera are exposed to the air in the course of the process of preparation must be separated by a sufficient distance from stables and animal houses to avoid the risk of aerial contamination with bacteria from animal excreta, and must be rendered fly-proof to prevent such contamination by insects. Such laboratories must have impervious walls and floors and must be capable of being readily disinfected when necessary.

(2) A special room with impervious walls and floor which can be washed and when necessary, chemically disinfected must be provided for the collection of blood from the living animal.

(3) An efficient system of manure removal must be used, which will prevent in accumulation in the vicinity of any room where blood or serum is collected or handled.

(4) An adequate number of efficient sterilizers must be provided for the sterilization of all glassware or other apparatus with which the serum may come into contact in the course of its preparation.

(5) All processes to which the serum is subjected during and after its collection from the animal, must be designed to preserve its sterility, but in the case of artificially concentrated sera, it shall suffice that the process of concentration is conducted with scrupulous cleanliness and in such a manner as to avoid unnecessary or dangerous contamination.

(6) The laboratories in which the testing of the sera for potency, sterility and freedom from abnormal toxicity are carried out must be adequate for the purpose. An adequate supply of animals for use in such tests and suitable housing for such animals must be provided.

(7) Provision must be made for complying with any special condition which may be laid down in this Schedule relating to the production and issue of the particular serum, in respect of which the licence is granted.

4. *Unhealthy or infected animals*—If an animal used in the production of sera is found to be suffering from an infection, except one produced by living organisms against which it is being immunized, or shows signs of serious or persistent ill-health not reasonably attributable to the process of immunization, the licensee shall immediately report the matter to the Licensing Authority and shall, if the authority orders an inspection and the Inspector so directs, cause such animal to be killed and a *post mortem* examination of it to be made, and take steps to prevent any serum obtained from the animal being sold or offered for sale until permission is given by the authority. If the result of the *post mortem* examination is such as to bring under suspicion the health of any of the other animals used for the production of sera, the Licensing Authority may prohibit the use of those animals for the production of sera or may take such other steps as may be necessary to prevent the issue of sera which may be dangerous to human health :

Provided in the case of emergency the person in charge of the establishment may order the destruction of an animal used in the production of sera and suspected of infection, and shall in that case give notice forthwith to the Licensing Authority and shall permit an Inspector to be present at the *post mortem* examination.

PART IV—PROVISIONS APPLICABLE TO PARTICULAR SERA AND ANTI-TOXIN

(A) PROVISIONS APPLICABLE TO ANTI-BACTERIAL SERA AND ANTI-TOXIC SERA FOR WHICH NO POTENCY TEST IS PRESCRIBED

(NOTE—The sera and anti-toxins to which this Part of this Schedule applies are the sera or solutions of the purified proteins of sera separated from the blood of animals which have been artificially immunized against cultures of one or more organisms or against a soluble toxin or toxins produced by the organism or organisms or against antigenic substances prepared from the organism or organisms.)

1. *Proper name*—The proper name of any anti-bacterial serum to which Division A of this Part of this Schedule applies shall be the recognized scientific name of the organisms or some generally recognized abbreviation thereof, preceded by the prefix “anti”, and followed by the word “serum”, as, for example, “Anti-meningococcus Serum”.

The proper name of any anti-toxin serum may be formed from the word “anti-toxin”, preceded by the name of the organism from which the toxin was prepared, and followed, if desired, by a term indicating the source or the strain of that organism, for example, “Streptococcus Anti-toxin (Scarlatina)”.

2. *Quality*—(1) Any such serum shall be issued for therapeutic use in the form of either—

- (a) natural serum, i.e., the liquid product of decantation of the coagulated blood or plasma without any addition, other than antiseptic, or subtraction; or
- (b) a solution of the purified serum proteins containing the specific antibodies.

(2) At the time of issue, the liquid shall be clear or show, at most a slight opalescence or precipitate. Preparations of the natural serum shall not contain more than 10 per cent of solid matter. A solution of the serum protein shall not contain more than 20 per cent of the solid matter.

3. *Labelling*—(1) The label on the container shall indicate the total number of c.c. in the container.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular product, that is to say, whether natural serum, or a solution of the purified serum proteins.

4. *Cultures*—The cultures used in immunizing the animals shall be at all times open to inspection, and specimens shall be furnished for examination at the request of the Licensing Authority.

5. *Records*—(1) The permanent records which the licensee is required to keep shall include the following particulars—

(a) as to the cultures—

- (i) the source from which the culture was obtained;
- (ii) the nature of the material from which the culture was isolated and the date of its isolation; and
- (iii) evidence of the identity and specificity of the culture.

(b) as to the procedure used in immunizing the animals—

- (i) the method of preparing the culture or antigen used for immunization;
- (ii) the dosage and methods employed in administering the culture of antigen;
- (iii) the period in the course of immunization at which blood is withdrawn for preparation of the serum.

(c) any test which may have been applied to the serum to determine its content of specific antibodies or its specific therapeutic potency.

(2) If the licensee desires to treat the performance of any tests recorded under sub-paragraph (1)(c) of this paragraph as determining the date of completion of manufacture for the purposes of Rule 109 he shall submit full particulars of the proposed test to the Licensing Authority and obtain his approval.

(B) PROVISIONS APPLICABLE TO ANTI-DYSENTERY SERUM (SHIGA) AND OTHER ANTI-DYSENTERY SERA

ANTI-DYSENTERY SERUM (SHIGA)

1. *Proper Name*—Anti-dysentery serum (Shiga) is the serum or the globulins containing the specific immune substances, separated from the blood of animals which have been immunized against the toxins, cultures or bacterial substances obtained by artificial culture of the *Bacillus dysenteriae* (Shiga). The proper name of the substance is "Anti-Dysentery Serum (Shiga)".

2. *Standard preparation*—The standard preparation is a quantity of dried serum, obtained from horses immunized against the toxic constituents

of the *Bacillus dysenteriae* (Shiga), and kept in the National Institute for Medical Research, Hampstead.

3. *Quality*—(1) Anti-dysentery serum (Shiga) shall be issued for therapeutic use in the form of either—

- (a) the serum separated from the blood or plasma of the immunized animals; or
- (b) the solution of the globulins containing the specific immune substances; or
- (c) a dry powder prepared from (i) the natural serum or (ii) the globulins containing the specific immune substances.

(2) If issued in fluid form the liquid shall, at the time of issue be clear or show, at the most, a very slight opalescence or precipitate. Preparations of the natural serum (the liquid product of decantation, of the coagulated blood without any addition, other than antiseptic, or subtraction) shall not contain more than 10 per cent of total solid matter. A solution of the separated antitoxic globulins shall not contain more than 20 per cent of total solid matter.

4. *Strength*—(1) The potency of anti-dysentery serum with respect to its content of antibodies for the toxic constituents of the *Bacillus dysenteriae* (Shiga) shall be determined by intravenous injection into mice of mixtures of the serum with a solution or suspension of the said toxic constituents, which solution or suspension has been standardized in relation to the standard preparation of anti-dysentery serum.

(2) Each container of anti-dysentery serum (Shiga) shall contain a sufficient number of units in excess of the minimum total number of units indicated on the label to ensure that the said minimum total number of units will still be present in the container at the date appearing on the label pursuant to Rule 109(1)(c) as the date upto which the preparation may be expected to retain its potency.

5. *Unit of standardization*—The unit of anti-dysentery serum (Shiga) for the purposes of these Rules is the specific neutralizing activity for the *Bacillus dysenteriae* (Shiga) contained in such an amount of the standard preparation as the Medical Research Council in the United Kingdom may from time to time indicate as the quantity exactly equivalent to the unit accepted for international use.

6. *Labelling*—(1) The label on the container shall indicate—

- (a) the minimum total number of units in the container; and
- (b) either (i) the potency of the preparation with respect to its anti-toxic value for the toxic constituents of the *Bacillus dysenteriae* (Shiga), expressed as the minimum number of units per c.c. in the case of liquid products, or as the minimum number of units per gramme in the case of dry products; or (ii) the total number of c.c. in the container.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular product, that is to say, whether natural serum, a solution of the globulins containing the specific immune substances, or a dried natural serum or dried globulins.

OTHER ANTI-DYSENTERY SERA

7. *Proper Names*—Anti-dysentery sera prepared by immunizing animals against bacilli producing dysentery in man, other than the *B. dysenteriae* (*Shiga*), shall conform with the provisions of Division (A) of this Part of this Schedule which are applicable to sera for which no potency test is prescribed. The proper name shall in each case be "Anti-dysentery Serum", followed, in brackets, by the personal name or other symbol by which the particular strain or strains of dysentery bacilli are identified by bacteriologists, as for example, "Anti-dysentery Serum (Flexner)", "Anti-dysentery Serum (Y)", "Anti-dysentery Serum (Flexner, Y)".

8. *Mixed sera*—A mixed anti-dysentery serum, prepared by immunizing animals against the *B. dysenteriae* (*Shiga*) and in addition against one or more of the other bacilli associated with human dysentery shall conform with the provisions of Division (A) of this Part of the Schedule, and shall also, with respect to its content of immune substance for the *B. dysenteriae* (*Shiga*) and its products, conform with paragraphs 3, 4, 5 and 6(2) in Division (B) thereof; and the number of unit shown on the label shall indicate the neutralizing value of the serum for the products of the *B. dysenteriae* (*Shiga*) only. The proper name of such a serum shall be "Anti-dysentery Serum" followed, in brackets, by the names of symbols indicating the strains used in its preparation, as for example, "Anti-dysentery Serum (*Shiga*, Flexner Y)".

(C) PROVISIONS APPLICABLE TO DIPHTHERIA ANTI-TOXIN

1. *Definition and Proper Name*—Diphtheria anti-toxin is the serum or the anti-toxic globulins separated from the blood of animals which have been immunized against diphtheria toxin. When the serum or anti-toxic globulins are obtained from the blood of horses or other equidae, the proper name of the substance is "diphtheria anti-toxin". When the serum or anti-toxic globulins are obtained from animals other than horses or other equidae, the proper name is "Diphtheria Anti-toxin" followed by the common name of the animal from which the substance is prepared.

2. *Standard preparation*—The standard preparation is a quantity of dried diphtheria anti-toxin kept in the National Institute for Medical Research, Hampstead, London.

3. *Strength*—(1) Diphtheria anti-toxin having a potency of less than 400 units per c.c. in the case of liquid preparations, or less than 4,000 units per gramme in the case of dried preparations shall not be issued.

(2) Each container of diphtheria anti-toxin shall contain a sufficient number of units in excess of the minimum total number of units indicated on the label to ensure that the said minimum total number of units will still be present in the container at the date appearing on the label pursuant to Rule 109(1)(c) as the date up to which the preparation may be expected to retain its potency.

4. *Quality*—(1) Diphtheria anti-toxin shall be issued for therapeutic and prophylactic use in the form of either—

(a) the serum separated from the blood or plasma of animals immunized against diphtheria toxin; or

- (b) the solution of the globulins containing the specific anti-toxin;
or
- (c) a dry powder prepared from (i) the natural serum or (ii) the anti-toxic globulins containing no antiseptic or other added substance.

(2) If issued in fluid form the liquid at the time of issue shall be clear or shall show, at the most, a very slight opalescence or precipitate. Preparations of the natural serum (the liquid product of decantation of the coagulated blood without any addition, other than antiseptic or subtraction) shall not contain more than 10 per cent of solid matter. A solution of the separated anti-toxic globulins shall not contain more than 0.1 gramme of solid matter for each 500 anti-toxin units.

5. *Unit of standardization*—The unit of diphtheria anti-toxin for the purposes of these Rules is the specific neutralizing activity for diphtheria toxin contained in such an amount of the standard preparation as the Medical Research Council in the United Kingdom may from time to time indicate as the quantity exactly equivalent to the unit accepted for international use.

6. *Tests for potency*—The potency in units of diphtheria anti-toxin shall be determined in accordance with a method approved by the Licensing Authority by the injection into guinea-pigs of a mixture consisting of the anti-toxin under test and of a diphtheria toxin which has been standardized in relation to the standard preparation.

7. *Labelling*—(1) The label on the container shall indicate—

- (a) the minimum total number of units in the container; and
- (b) either (i) the potency of the preparation expressed as the minimum number of units of anti-toxin per c.c. in the case of liquid products, or as the minimum number of units of anti-toxin per gramme in the case of dry products; or (ii) the total number of c.c. in the container.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular product, that is to say, whether natural serum, or a solution of anti-toxic globulins, dried natural serum, or dried anti-toxic globulins.

(D) PROVISIONS APPLICABLE TO TETANUS ANTI-TOXIN

1. *Proper Name*—Tetanus anti-toxin is the serum, or the anti-toxic globulins separated from the blood of animals which have been immunized against tetanus toxin. The proper name of the substance is "Tetanus Anti-toxin".

2. *Standard preparation*—The standard preparation is a quantity of dried tetanus anti-toxin kept in the National Institute for Medical Research, Hampstead, London.

3. *Strength*—(1) Tetanus anti-toxin having a potency of less than 150 units per c.c. in the case of liquid preparations or less than 1,500 units per gramme in the case of dried preparations, shall not be issued for prophylactic use.

Tetanus anti-toxin having a potency of less than 800 units per c.c. in the case of liquid preparations, or less than 8,000 units per gramme in the case of dried preparations shall not be issued for the treatment of tetanus.

(2) Each container of tetanus anti-toxin shall contain a sufficient number of units in excess of the minimum total number of units indicated on the label to ensure that the said minimum total number of units will still be present in the container at the date appearing on the label pursuant to Rule 109(1)(c) as the date upto which the preparation may be expected to retain its potency.

4. *Quantity*—(1) Tetanus anti-toxin shall be issued for therapeutic and prophylactic use in the form of either—

- (a) the serum separated from the blood or plasma of animals immunized against tetanus toxin; or
- (b) the solution of the globulins containing the specific anti-toxin, or
- (c) a dry powder prepared from (i) the natural serum, or (ii) the anti-toxic globulins, and containing no antiseptic or other added substance.

(2) If issued in fluid form the liquid at the time of issue shall be clear or show at the most a very slight opalescence or precipitate. Preparations of the natural serum (the liquid product of decantation of the coagulated blood without any addition, other than antiseptic, or subtraction) shall not contain more than 10 per cent of total solid matter. A solution of the separated anti-toxic globulins shall not contain more than 0.1 gramme of solid matter for each 300 anti-toxin units.

5. *Unit of Standardization*—The unit of tetanus anti-toxin for the purposes of these Rules is the specific neutralizing activity for tetanus toxin contained in such an amount of the standard preparation as the Medical Research Council in the United Kingdom may from time to time indicate as the quantity exactly equivalent to the unit accepted for international use.

6. *Test of potency*—The potency in units of tetanus anti-toxin shall be determined by the subcutaneous injection into guinea-pigs or mice of mixtures of the preparation with a tetanus toxin which has been standardized in relation to the standard preparation of tetanus anti-toxin. The neutralizing value may be determined by observation either—

- (a) of the greatest dose which fails to protect a guinea-pig or mouse from death within four days, or
- (b) of the least dose, which suffices to protect a mouse or guinea-pig from the appearance of symptoms of tetanus.

7. *Labelling*—(1) The label on the container shall indicate—

- (a) the minimum total number of units in the container; and
- (b) either (i) the potency of the preparation expressed as the minimum number of units of anti-toxin per c.c. in the case of liquid products, or as the minimum number of units of anti-toxin per gramme in the case of dry products; or (ii) the total number of c.c. in the container.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular products, that is to say, whether natural serum, a solution of anti-toxic globulins, dried natural serum, or dried anti-toxin globulins.

(This Section D has been revised under Government of India Notification No. F. 1-1/52-DS, dated the 20th July, 1953).

(E) PROVISIONS APPLICABLE TO GAS-GANGRENE ANTI-TOXIN
(PERFRINGENS)

1. *Proper Name*—Gas-Gangrene Anti-toxin (Perfringens) is the serum or the anti-toxic globulins, separated from the blood of animals which have been immunized against the specific toxin prepared by the growth of *Bacillus perfringens* (*B. welchii*) in a fluid medium. The proper name of the substance is "Gas-Gangrene Anti-toxin (Perfringens)".

2. *Standard preparation*—The standard preparation is a quantity of dried gas-gangrene anti-toxin (perfringens) kept in the National Institute for Medical Research, Hampstead, London.

3. *Quality*—(1) Gas-gangrene anti-toxin shall be issued for therapeutic use in the form of either—

- (a) the serum separated from the blood or plasma of the immunized animals; or
- (b) the solution of the globulins containing the specific immune substances; or
- (c) a dry powder prepared from (i) the natural serum or (ii) the globulin containing the specific immune substances.

(2) If issued in fluid form the liquid shall, at the time of issue, be clear or show, at the most, a very slight opalescence or precipitate. Preparation of the natural serum (the liquid product of decantation of the coagulated blood without any addition, other than antiseptic, or subtraction) shall not contain more than 10 per cent of solid matter. A solution of the separated anti-toxic globulins shall not contain more than 20 per cent of total solid matter.

4. *Strength*—(1) The potency in units of gas-gangrene anti-toxin (perfringens) shall be determined, in accordance with a method approved by the Licensing Authority, by the injection into animals of a mixture of the anti-toxin under test with a gas-gangrene (perfringens) toxin which has been standardized in relation to the standard preparation of gas-gangrene anti-toxin (perfringens).

(2) Each container of gangrene anti-toxin (perfringens) shall contain a sufficient number of units in excess of the minimum total number of units indicated on the label to ensure that the said minimum total number of units will still be present in the container at the date appearing on the label pursuant to rule 109(1)(c) as the date up to which the preparation may be expected to retain its potency.

5. *Units of Standardization*—The unit of gas-gangrene anti-toxin (perfringens) for the purposes of these Rules is the specific neutralizing activity for gas-gangrene (perfringens) toxin contained in such an amount of the standard preparation as the Medical Research Council in the United Kingdom may from time to time indicate as the quantity exactly equivalent to the unit accepted for international use.

6. *Labelling*—(1) The label on the container shall indicate—

- (a) the minimum total number of units in the container; and
- (b) either (i) the potency of the preparation expressed as the minimum number of units of anti-toxin per c.c. in the case of liquid products or as minimum number of units of anti-toxin per gramme in the case of dry products; or (ii) the total number of c.c. in the container.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular product, that is to say, whether natural serum, a solution of anti-toxic globulins, dried natural serum or dried anti-toxic globulins.

7. *Mixed anti-toxins*—Mixed anti-toxin, containing anti-toxin against other toxins than that of the *Bacillus perfringens*, shall, with respect to its content in units of gas-gangrene anti-toxin (perfringens), conform with paragraphs 4, 5 and 6.

(F) PROVISIONS APPLICABLE TO GAS-GANGRENE ANTI-TOXIN
(OEDEMATIENS)

1. *Proper Name*—Gas-Gangrene Anti-toxin (Oedematiens) is the serum, or the anti-toxic globulins, separated from the blood of animals which have been immunized against the specific toxin prepared by the growth of *Clostridium oedematiens* in a fluid medium. The proper name of the substance is "Gas-Gangrene Anti-toxin (Oedematiens)".

2. *Standard preparation*—The standard preparation is a quantity of dried gas-gangrene anti-toxin (Oedematiens) kept in the National Institute for Medical Research, Hampstead, London.

3. *Quality*—(1) Gas-Gangrene Anti-toxin (Oedematiens) shall be issued for therapeutic use in the form of either—

- (a) the serum separated from the blood or plasma of the immunized animals; or
- (b) the solution of the globulins containing the specified immune substances; or
- (c) the dried solid prepared from (i) the natural serum or (ii) the globulins containing the specified immune substances.

(2) If issued in fluid form the liquid shall, at the time of issue, be clear or show, at the most, a very slight opalescence or precipitate. Preparation of the natural serum (the liquid product of decantation of the coagulated blood or plasma, without any addition, other than antiseptic, or subtraction shall not contain more than 10 percent of solid matter. A solution of the separated anti-toxic globulins shall not contain more than 20 per cent of total solid matter.

4. *Strength*—(1) The potency in units of gas gangrene anti-toxin (Oedematiens) shall be determined by a method approved by the licensing Authority by the injection into animals of a mixture of the anti-toxin under test with a gas-gangrene (Oedematiens) toxin which has been standardized in relation to the standard preparation of gas-gangrene anti-toxin (Oedematiens).

(2) Each container of gas-gangrene anti-toxin (Oedematiens) shall contain a sufficient number of units in excess of the minimum total number of units indicated on the label to ensure that the said minimum total number of units will still be present in the container at the date appearing on the label pursuant to Rule 109(1)(c) as the date up to which the preparation may be expected to retain its potency.

5. *Unit of Standardization*—The unit of gas-gangrene anti-toxin (Oedematiens) for the purposes of these Rules is the specific neutralizing activity for gas-gangrene (Oedematiens) toxin contained in such an amount of the standard preparation as the Medical Research Council in the United

Kingdom may from time to time indicate as the quantity exactly equivalent to the unit accepted for international use.

6. *Labelling*—(1) The label on the container shall indicate—

- (a) the minimum total number of units in the container; and
- (b) either (i) the potency of the preparation expressed as the minimum number of units of anti-toxin per c.c. in the case of liquid products or as minimum number of units of anti-toxin per gramme in the case of dry products; or (ii) the total number of c.c. in the container.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular product, that is to say, whether natural serum, a solution of anti-toxic globulins, dried natural serum or dried anti-toxin globulins.

7. *Mixed anti-toxin*—The mixed anti-toxin, containing anti-toxins against other toxins than that of *Clostridium oedematiens* shall, with respect to its content in units of gas-gangrene anti-toxin (Oedematiens) conform with paragraphs 4, 5 and 6.

(G) PROVISIONS APPLICABLE TO GAS-GANGRENE ANTI-TOXIN (VIBRION SEPTIQUE)

1. *Proper Name*—Gas-gangrene Anti-toxin (Vibrion Septique) is the serum or the anti-toxic globulins, separated from the blood of animals which have been immunized against the specific toxin prepared by the growth of the clostridium commonly known as vibrion septique in a fluid medium. The proper name of the substance is "Gas-Gangrene Anti-toxin (Vibrion Septique)".

2. *Standard preparation*—The standard preparation is a quantity of dried gas-gangrene anti-toxin (Vibrion Septique) kept in the National Institute for Medical Research, Hampstead, London.

3. *Quality*—(1) Gas-gangrene Anti-toxin (Vibrion Septique) shall be issued for therapeutic use in the form of either—

- (a) the serum separated from the blood or plasma of the immunised animals; or
- (b) the solution of the globulins containing the specified immune substances; or
- (c) the dried solid prepared from (i) the natural serum or (ii) the globulins containing the specified immune substances.

(2) If issued in fluid form the liquid shall, at the time of issue, be clear or show, at the most, a very slight opalescence or precipitate. Preparations of the natural serum (the liquid product of decantation of the coagulated blood without any addition, other than antiseptic, or subtraction) shall not contain more than 10 per cent of solid matter. A solution of the separated anti-toxic globulins shall not contain more than 20 per cent of solid matter.

4. *Strength*—(1) The potency in units of gas-gangrene anti-toxin (Vibrion Septique) shall be determined, by a method approved by the Licensing Authority, by the injection into animals of a mixture of the anti-toxin under test with a gas-gangrene (Vibrion Septique) toxin which has

been standardized in relation to the standard preparation of gas-gangrene anti-toxin (Vibron Septique).

(2) Each container of gas-gangrene anti-toxin (Vibron Septique) shall contain a sufficient number of units in excess of the minimum total number of units indicated on the label to ensure that the said minimum total number of units will still be present in the container at the date appearing on the label pursuant to Rule 109(1)(c) as the date up to which the preparation may be expected to retain its potency.

5. *Unit of standardization*—The unit of gas-gangrene anti-toxin (Vibron Septique) for the purposes of these Rules is the specific neutralizing activity for gas-gangrene (Vibron Septique) toxin contained in such an amount of the standard preparation as the Medical Research Council in the United Kingdom may from time to time indicate as the quantity exactly equivalent to the unit accepted for international use.

6. *Labelling*—(1) The label on the container shall indicate—

- (a) the minimum total number of units in the container; and
- (b) either (i) the potency of the preparation expressed as the minimum number of units of anti-toxin per c.c. in the case of liquid products or as minimum number of units of anti-toxin per gramme in the case of dry products; or (ii) the total number of c.c. in the container.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular product, that is to say, whether natural serum, a solution of anti-toxic globulins, dried natural serum or dried anti-toxic globulins.

7. *Mixed anti-toxin*—A mixed anti-toxin, containing anti-toxin against other toxins than that of the clostridium commonly known as vibron septique shall, with respect to its content in units of gas-gangrene anti-toxin (Vibron Septique) conform with paragraphs 4, 5 and 6.

(H) PROVISIONS APPLICABLE TO GAS-GANGRENE ANTI-TOXIN (HISTOLYTICUS)

1. *Proper Name*—Gas-gangrene Anti-toxin (Histolyticus) is the serum or the anti-toxic globulins, separated from the blood of animals which have been immunized against the specific toxin prepared by the growth of *Clostridium histolyticus* in the fluid medium. The proper name of the substance is "Gas-Gangrene Anti-toxin (Histolyticus)".

2. *Standard preparation*—The standard preparation is a quantity of dried gas-gangrene anti-toxin (histolyticus) kept in the National Institute for Medical Research, Hampstead, London.

3. *Quality*—(1) Gas-Gangrene Anti-toxin (Histolyticus) shall be issued for therapeutic use in the form of either—

- (a) the serum separated from the blood or plasma of the immunized animals; or
- (b) the solution of the globulins containing the specified immune substances; or
- (c) the dried solid prepared from (i) the natural serum or (ii) the globulins containing the specified immune substances.

(2) If issued in fluid form the liquid shall, at the time of issue, be clear or show, at the most, a very slight opalescence or precipitate. Preparations of the natural serum (the liquid product of decantation of the coagulated blood or plasma without any addition, other than antiseptic, or subtraction) shall not contain more than 10 per cent of solid matter. A solution of the separated anti-toxic globulins shall not contain more than 20 per cent of solid matter.

4. *Strength*—(1) The potency in units of gas-gangrene anti-toxin (histolyticus) shall be determined in accordance with a method approved by the Licensing Authority, by the injection into animals of a mixture of the anti-toxin under test with gas-gangrene (histolyticus) toxin which has been standardized in relation to the standard preparation of gas-gangrene anti-toxin (histolyticus).

(2) Each container of gas-gangrene anti-toxin (histolyticus) shall contain a sufficient number of units in excess of the minimum total number of units indicated on the label to ensure that the said minimum total number of units will still be present in the container at the date appearing on the label pursuant to Rule 109(1)(c) of these Rules as the date up to which the preparation may be expected to retain its potency.

5. *Unit of standardization*—The unit of gas-gangrene anti-toxin (histolyticus) for the purpose of these Rules is the specific neutralizing activity for gas-gangrene (Histolyticus) toxin contained in such an amount of the standard preparation as the Medical Research Council in the United Kingdom may from time to time indicate as the quantity exactly equivalent to the unit accepted for international use.

6. *Labelling*—(1) The label on the container shall indicate—

(a) the minimum total number of units in the container; and

(b) either (i) the potency of the preparation expressed as the minimum number of units of anti-toxin per c.c. in the case of liquid products or as minimum number of units of anti-toxin per gramme in the case of dry products; or (ii) the total number of c.c. in the container.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular product, that is to say, whether natural serum, a solution of anti-toxic globulins, dried natural serum or dried anti-toxic globulins.

7. *Mixed anti-toxin*—A mixed anti-toxin containing anti-toxins against other toxins than that of *Clostridium histolyticus* shall with respect to its content in units of gas-gangrene anti-toxin (histolyticus), conform with paragraphs 4, 5 and 6.

(I) PROVISIONS APPLICABLE TO ANTI-PNEUMOCOCCUS SERUM (TYPE I)

1. *Proper Name*—Anti-pneumococcus Serum (Type I) is the serum, or the globulins containing the specific immune substances, separated from the blood of animals which have been immunized against cultures of a Pneumococcus (*Diplococcus pneumoniae*) of the variety known as Type I. The proper name of the substance is "Anti-pneumococcus Serum (Type I)".

2. *Standard preparation*—The standard preparation is a quantity of dried anti-pneumococcus serum (Type I) kept at the National Institute for Medical Research, Hampstead, London.

3. *Quality*—(1) Anti-pneumococcus Serum (Type I) shall be issued for therapeutic use in the form of either—

- (a) the serum separated from the blood or plasma of the immunized animals; or
- (b) the solution of the globulins containing the specific immune substances; or
- (c) the dried solid prepared from (i) the natural serum or (ii) the globulins containing the specific immune substances.

(2) If issued in fluid form the liquid shall, at the time of issue, be clear or show, at the most, a slight opalescence or precipitate. Preparation of the natural serum (the liquid product of the decantation of the coagulated blood or plasma without any addition, other than antiseptic, or subtraction) shall not contain more than 10 per cent of total solid matter. A solution of the separated globulins shall not contain more than 20 per cent of total solid matter.

4. *Strength*—The potency in units of anti-pneumococcus serum (Type I) shall be determined in accordance with a method approved by the Licensing Authority, by comparison of the activity of the serum under test in protecting animals against the lethal action of a virulent culture of *Diplococcus pneumoniae* (Type I) with the activity under identical conditions of the standard preparation of anti-pneumococcus serum (Type I).

5. *Unit of standardization*—The unit of anti-pneumococcus serum (Type I) for the purposes of these Rules is that quantity of the standard preparation which the Medical Research Council in the United Kingdom may from time to time indicate as the quantity exactly equivalent to the unit accepted for international use.

6. *Labelling*—(1) The label on the container shall indicate—

- (a) the minimum total number of units in the container; and
- (b) either (i) the potency of the preparation expressed as the minimum number of units per c.c. in the case of liquid products or as minimum number of units per gramme in the case of dry products; or (ii) the total number of c.c. in the container.

(2) The label on the container or the label or wrapper on the package, shall indicate the nature of the particular product, that is to say, whether natural serum, a solution of anti-toxic globulins, dried natural serum or dried anti-toxic globulins.

(3) The date to be indicated under Rule 109(1)(c) shall not be later than two years after the date of manufacture.

7. *Mixed anti-pneumococcus Sera*—A mixed anti-pneumococcus serum containing anti-bodies against strains of *Diplococcus pneumoniae* other than those of the variety known as Type I, shall with respect to its content in units of anti-pneumococcus serum (Type I) conform with paragraphs 4, 5 and 6 of this part.

(J) PROVISIONS APPLICABLE TO ANTI-PNEUMOCOCCUS SERUM (TYPE II)

1. *Proper Name*—Anti-pneumococcus Serum (Type II) is the serum, or the globulins containing the specific immune substances separated from the blood of animals which have been immunized against cultures of a

pneumococcus (*Diplococcus pneumoniae*) of the variety known as *Type II*. The proper name of the substance is "Anti pneumococcus Serum (Type II)".

2. *Standard preparation*—The standard preparation is a quantity of dried anti-pneumococcus serum (Type II) kept at the National Institute for Medical Research, Hampstead, London.

3. *Quality*—(1) Anti-pneumococcus Serum (Type II) shall be issued for therapeutic use in the form of either—

- (a) the serum separated from the blood or plasma of the immunized animals; or
- (b) the solution of the globulins containing the specific immune substances; or
- (c) the dried solid prepared from (i) the natural serum or (ii) the globulins containing the specific immune substances.

(2) If issued in fluid form the liquid shall, at the time of issue, be clear or show, at the most, a slight opalescence or precipitate. Preparations of the natural serum (the liquid product of the decantation of the coagulated blood or plasma without any addition, other than antiseptic, or subtraction) shall not contain more than 10 per cent of total solid matter. A solution of the separated globulins shall not contain more than 20 per cent of total solid matter.

4. *Strength*—The potency in units of anti-pneumococcus serum (Type II) shall be determined, in accordance with a method approved by the Licensing Authority, by comparison of the activity of the serum under test in protecting animals against the lethal action of a virulent culture of *Diplococcus pneumoniae* (Type II) with the activity under identical conditions of the standard preparation of anti-pneumococcus serum (Type II).

5. *Unit of standardization*—The unit of anti-pneumococcus serum (Type II) for the purpose of these Rules is that quantity of the standard preparation which the Medical Research Council in the United Kingdom may from time to time indicate as the quantity exactly equivalent to the unit accepted for international use.

6. *Labelling*—(1) The label on the container shall indicate—

- (a) the minimum total number of units in the container; and
- (b) either (i) the potency of the preparation expressed as the minimum number of the units per c.c. in the case of liquid products or as the minimum number of units per gramme in the case of dry products; or (ii) the total number of c.c. in the container.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular product, that is to say, whether natural serum, a solution of anti-toxic globulins, dried natural serum or dried anti-toxic globulins.

(3) The date to be indicated under Rule 109(1)(c) shall not be later than two years after the date of manufacture.

7. *Mixed anti-pneumococcus sera*—A mixed anti-pneumococcus serum containing anti-bodies against strains of *Diplococcus pneumoniae* other than those of the variety known as *Type II*, shall with respect to its content in

units of anti-pneumococcus serum (Type II) conform with paragraphs 4, 5 and 6.

(K) PROVISIONS APPLICABLE TO STAPHYLOCOCCUS ANTI-TOXIN

1. *Proper Name*—Staphylococcus anti-toxin is the serum, or the anti-toxic globulins, separated from the blood of animals, which have been immunized against the toxin prepared by artificial culture on suitable media of Staphylococci obtained from cases of infection. The staphylococcus toxin is characterized by its lethal action when injected into susceptible animals, by the production of inflammation and necrosis when injected intracutaneously into susceptible animals, and by its lytic action *in vitro* on the red blood corpuscles of the rabbit. Staphylococcus anti-toxin is characterized by its power of neutralizing these activities of the staphylococcus toxin when mixed with it in effective proportions. The proper name of the substance is "Staphylococcus Anti-toxin".

2. *Standard preparation*—The standard preparation is a quantity of dried staphylococcus anti-toxin kept in the National Institute for Medical Research, Hampstead, London.

3. *Quality*—(1) Staphylococcus anti-toxin shall be issued for therapeutic use in the form of either—

- (a) the serum separated from the blood or plasma of the immunized animals; or
- (b) the solution of the globulins containing the specific immune substances; or
- (c) the dried solid prepared from (i) the natural serum or (ii) the globulins containing the specific immune substances.

(2) If issued in fluid form the liquid shall, at the time of issue, be clear or show, at the most, a very slight opalescence or precipitate. Preparations of the natural serum (the liquid product of decantation of the coagulated blood or plasma without any addition, other than antiseptic or subtraction) shall not contain more than 10 per cent of solid matter. A solution of the separated anti-toxic globulin shall not contain more than 20 per cent of total solid matter.

4. *Strength*—(1) The potency in units of staphylococcus anti-toxin shall be determined, in accordance with a method approved by the Licensing Authority and based on the specific neutralizing action of the anti-toxin under test on a staphylococcus toxin which has been standardized in relation to the standard preparation of staphylococcus anti-toxin.

(2) Each container of staphylococcus anti-toxin shall contain a sufficient number of units in excess of the total minimum of units indicated on the label to ensure that the said minimum total number of units will still be present in the container at the date appearing on the label pursuant to Rule 109(1)(c) as the date upto which the preparation may be expected to retain its potency.

5. *Unit of Standardization*—The unit of staphylococcus anti-toxin for the purposes of these Rules is the specific neutralizing activity for staphylococcus toxin contained in such an amount of the standard preparation as the Medical Research Council in the United Kingdom may from time to time indicate as the quantity exactly equivalent to the unit accepted for international use.

6. *Labelling*—(1) The label on the container shall indicate—

- (a) the minimum total number of units in the container; and
- (b) either (i) the potency of the preparation expressed as the minimum number of units of anti-toxin per c.c. in the case of liquid products, or as the minimum number of units of anti-toxin per gramme in the case of dry products; or (ii) the total number of c.c. in the container.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular product, that is to say, whether natural serum, a solution of anti-toxic globulins, dried natural serum or dried anti-toxic globulins.

(L) PROVISIONS APPLICABLE TO ANTI-VENOM SERUM (ANTI-VENENE)

1. *Proper Name*—Anti-venom Serum (or anti-venene) is the serum or the globulins containing the specific neutralizing substances separated from the blood of animals which have been immunized against the venom of the one or more poisonous snakes. The proper name of the substances is Anti Venom Serum (or Anti-venene) followed by names of the species of snakes against the venoms of which it has been prepared.

2. *Standard preparations*—The standard preparations are quantities of the dried venom of the Indian Cobra (*Naja tripudians*) Russel's Viper (*Vipera russellii*) kept at the Central Research Institute, Kasauli.

3. *Quality*—(1) Anti-venom serum (or anti-venene) shall be issued for therapeutic use in the form of either—

- (a) the serum separated from the blood or plasma of immunized animals; or
- (b) the solution of the globulins containing the specific neutralizing substances; or
- (c) a dry powder prepared from (i) the natural serum or (ii) the globulins containing the specific neutralizing substances.

(2) If issued in fluid form the liquid shall, at the time of issue, be clear or show, at most, a very slight opalescence or precipitate. Preparations of the natural serum (the liquid product of decantation of the coagulated blood without any addition, other than antiseptic or subtraction) shall not contain more than 10 per cent of total solid matter. A Solution of the separated neutralizing globulins shall not contain more than 20 per cent of total solid matter.

4. *Strength*—(1) The potency of anti-venom serum (or antivenene) shall be determined in accordance with a method approved by the licensing Authority.

5. *Labelling*—(1) The label on the container shall indicate—

- (a) the potency of the preparation expressed as the weight of dried venom, each species of poisonous snakes against which it is prepared, is neutralized, under the method of test employed, by one cubic centimetre of the serum;
- (b) the total number of cubic centimetres in the container.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular product, that is to say, whether natural serum, or a solution of the globulins containing the specific neutralizing substances, or dried globulins.

PART V—ARSPHEVAMINE AND ITS DERIVATIVES

(A) GENERAL PROVISIONS APPLICABLE TO ARSPHENAMINE AND TO ITS DERIVATIVES

1. *Standard preparations*—The standard preparations of arsphenamine and of the derivatives thereof are quantities of those preparations kept in the National Institute for Medical Research, Hampstead, London.

2. *Biological tests*—(1) The tests shall be carried out either—

- (a) in a central institution appointed by the Licesing Authority; or
- (b) if the Licesing Authority so direct, the laboratories of the licensee.

(2) The licensee shall, if the Licesing Authority so direct, transmit to the appointed institution for testing a sample from each finished batch of arsphenamine, or its derivative, intended for issue. The sample shall consist of at least six sealed containers of the product as completed for issue, taken by random sampling from the whole batch, and each containing at least 0.6 gramme of the product. If the Licensing Authority direct that the test shall be carried out in the laboratories of the licensee, they shall be carried out in strict accordance with the directions given by the authority, and in comparison with the standard preparation of arsphenamine or the derivative thereof corresponding to the product under test.

(3) The tests shall consist of the following :

- (a) *The test for maximum toxicity*—Several separate containers for each finished batch shall be tested for toxicity by intravenous (or where the Part of this Schedule relating to a particular derivative requires, by subcutaneous) injection into at least ten mice and five rats, or into such number of animals of some other species as the Licensing Authority may consider equivalent, and no batch shall be passed for issue which shows a toxicity greater than that of the standard preparation when tested under identical conditions. The tests shall be conducted in accordance with such detailed instructions as the Licensing Authority may issue.
- (b) *Test for therapeutic potency*—Samples from each batch shall be tested for therapeutic potency on a series of mice or rats infected with a suitable strain of pathogenic trypanosomes (*T. brucie*, *T. equiperdum* etc.) in accordance with the following general method and with such detailed instructions as the Licensing Authority may issue (i) the mice or rats on which the test is made shall be infected with the trypanosome employed to an equal degree, the degree being determined by enumeration per unit volume of blood; (ii) samples from each batch shall be tested by means of several doses each of which shall be administered to at least five of the animals, and the result shall be evaluated by comparison with the

effects of the standard preparation, administered to animals of the same species, having the same degree of infection.

4. *Method of issue*—Arsphenamine and any derivative of arsphenamine shall be issued in the form of a dry powder either in evacuated glass containers or in glass containers which have been filled before being sealed with some inert gas to the exclusion of oxygen unless permission is given by Licensing Authority for the issue of a particular derivative in some other form.

(B) SPECIAL PROVISIONS APPLICABLE TO NEOARSPHENAMINE

1. *Proper Name*—Neoarsphenamine is the sodium salt of dioxydiamino arseno benzo-methylene sulphylic acid. Its proper name is "Neoarsphenamine".

2. *Quality*—Neoarsphenamine must have the following physical and chemical characteristics :—

- (a) the substance must be in the condition of a yellow dry powder, freely mobile in contact with glass surfaces, and without odour, except such as is due to traces of ether or alcohol;
- (b) the substance must be soluble in water, but insoluble in absolute ethyl alcohol and in ether. If 0.6 gramme of the substance is added to 1 cubic centimetre of distilled water, it must dissolve rapidly and completely and form a clear, yellow solution, mobile and free from gelatinous particles and suspended matter of every kind;
- (c) a normal solution of sodium carbonate or a 5 per cent solution of the anhydrous carbonate, added in equal volume to a 10 per cent aqueous solution of neoarsphenamine, must not produce a precipitate;
- (d) diluted hydrochloric acid (I.P.) added in equal volume to a 10 per cent aqueous solution of neoarsphenamine must give a yellow precipitate of the free acid from neoarsphenamine. If the mixture is warmed, sulphur dioxide must be evolved so as to be detected by iodate-starch paper;
- (e) when a solution of 0.2 gramme of neoarsphenamine in 10 c.c. of water is acidified with phosphoric acid and distilled to about one-half its volume, formaldehyde must be evolved so as to be detected in the distillate by a red ring formed at the line of contact when five drops of a 1 per cent solution of phenol is added and a layer of sulphuric acid is run under the mixture;
- (f) the dry powder, as taken directly from the ampoules in which it is issued, must contain not less than 18 per cent or more than 21 per cent of arsenic, as determined by a method approved by the Licensing Authority.

3. *Test for stability*—The product as filled into ampoules shall be kept at a temperature of 56°C for at least 24 hours and shall retain colour, physical properties and solubility substantially unchanged at the end of that period.

(C) SPECIAL PROVISIONS APPLICABLE TO SULPHARSPHENAMINE

1. *Proper Name*—Sulpharsphenamine is the sodium salt of dioxydiamino-arseno benzene-methylene-sulphurous acid. Its proper name is "Sulpharsphenamine".

2. *Quality*—Sulpharsphenamine must have the following physical and chemical characteristics :—

- (a) The substance must be in the condition of a yellow dry powder, freely mobile in contact with glass surfaces, and without odour, except that due to traces of ether or alcohol;
- (b) the substance must be soluble in water but insoluble in alcohol and in ether. If 0.6 grammes of the substance is added to 1 c.c. of distilled water, it must dissolve rapidly and completely, and form a clear yellow solution, mobile and free from gelatinous particles and suspended matter of every kind;
- (c) a normal solution of sodium carbonate or a 5 per cent solution of the anhydrous carbonate, added in equal volume to a 10 per cent aqueous solution of sulpharsphenamine must not produce a precipitate;
- (d) five volume of diluted hydrochloric acid (I.P.) added to one volume of a 10 per cent aqueous solution of sulpharsphenamine must give, after a few minutes, a yellow precipitate of the free acid from sulpharsphenamine. If the mixture is boiled, sulphur dioxide must be evolved so as to be detected by iodate-starch paper;
- (e) when a solution of 0.2 gramme of sulpharsphenamine in 10 c.c. of water is acidified with phosphoric acid and distilled to about one-half its volume formaldehyde must be evolved so as to be detected in the distillate by a red ring formed at the line of contact when five drops of a 1 per cent solution of phenol is added and a layer of sulphuric acid is run under the mixture;
- (f) on addition of an equal volume of 1 in 10,000 indigocarmine solution, a 10 per cent watery solution of sulpharsphenamine must not reduce the indigo-carmine in five minutes at 50°C;
- (g) the dry powder, as taken directly from the ampoules in which it is issued, must contain not less than 18 per cent or more than 21 per cent of arsenic as determined by a method approved by the Licensing Authority.

3. *Test for toxicity and therapeutic potency*—The test of maximum toxicity and for therapeutic potency prescribed in paragraph 2(3) of Section (A) of this Part of this Schedule shall, in the case of sulpharsphenamine, be carried out by subcutaneous injection into mice or rats.

4. *Test for stability*—The product as filled into ampoules shall be kept at 56°C for at least 24 hours and shall retain its colour, physical properties and solubility substantially unchanged at the end of that period.

(D) SPECIAL PROVISIONS APPLICABLE TO DERIVATIVES OF ARSPHENAMINE OTHER THAN THOSE SPECIFIED IN (B) AND (C) OF THIS PART

1. *Nature of substance*—In the case of any derivatives of arspenamine other than those specified in Section (B) and (C) of this Part of this Schedule the applicant for a manufacturing or an import licence shall

submit to the Licensing Authority with his application a statement of the true chemical nature and composition of the derivative, and a full and detailed account of the chemical tests by which that composition is determined and by which the uniformity of successive batches is secured.

2. *Proper Name*—The applicant shall also submit with his application the name which he proposes to use for the derivative to which the application relates and such name, if approved by the Licensing Authority, may be used as the proper name of the derivative.

3. *Chemical tests*—If a licence is granted for the manufacture of such a derivative of arsphenamine, the licensee shall carry out on each batch of the derivative such, if any, of the chemical tests submitted with the application as are accepted by the Licensing Authority, and any others which the authority may direct as requisite for determining the composition and securing its uniformity. No batch of the derivative which fails to pass any of the tests so accepted or directed shall be issued.

4. *Test for toxicity and potency*—Each batch of such derivative further be tested, by biological methods, for toxicity and potency, according to the methods prescribed in Section (A) of this Part of this Schedule. In the event of no standard preparation being available for a particular derivative, the tests shall be made in such form and their results interpreted in accordance with such criteria as the Licensing Authority may direct.

PART VI—INSULIN

1. *Proper Name*—Insulin is the preparation of the specific antidiabetic principle of the pancreas. Its proper name is "Insulin".

2. *Special conditions of licence*—It shall be a condition of every licence to manufacture or to import insulin :—

(a) that it shall not be issued in a mixture with any other therapeutic agent except with the previous consent of the licensing authority;

(b) that if issued for injection suspended in some medium in which it is not itself soluble, it shall be tested before suspension.

3. *Standard preparation*—The standard preparation is a quantity of dry soluble insulin hydrochloride prepared and kept in the National Institute for Medical Research, Hampstead, London.

4. *Unit of standardization*—The unit of insulin for the purposes of these Rules is the specific activity contained in such an amount of the standard preparation as the Medical Research Council in the United Kingdom may from time to time indicate as the quantity exactly equivalent to the unit accepted for international use.

5. *Quality*—The acidity of the prepared watery solution, as determined by a suitable indicator, shall be such that the hydrogen-ion concentration is not less than that corresponding to $pH=4$, or greater than that corresponding to $pH=3$.

6. *Test*—(1) The methods used for testing the potency of preparation in comparison with the standard preparation shall be such as the Licensing Authority may from time to time approve.

(2) In addition, samples from each batch shall be tested in such manner as the Licensing Authority may direct for the purpose of ascertaining its stability under ordinary conditions of storage.

7. *Container*—In the case of a prepared solution of insulin the glass of the container shall be non-alkaline resistance glass.

8. *Labelling*—In the case of prepared solution of insulin the label on the container shall indicate the strength as the number of units per c.c. and in the case of compressed tablets as the number of units in each tablet.

PART VII—PITUITARY (POSTERIOR LOBE) EXTRACT

1. *Proper Name*—Pituitary extract is the watery extract prepared from the separated posterior lobe of the pituitary body or the watery solution of one or more of the separated active principles of that lobe. The proper name of the complete water extract is "Pituitary (posterior lobe) Extract". The proper name of a solution containing one of the separated active principles is "Oxytocic principle of the pituitary posterior lobe" or "Pressor principle of the pituitary posterior lobe" or such other name descriptive of such a solution as the Licensing Authority may in any particular case approve in writing.

2. *Standard preparation*—The standard preparation is a quantity of dried acetone-extracted substance obtained from the posterior lobes of fresh pituitary bodies of oxen. The standard is kept in the National Institute for Medical Research, Hampstead, London.

3. *Unit of standardization*.—(1) The unit of pituitary extracts for the purposes of these Rules is the specific activity corresponding to that yielded by 0.5 milligramme of the standard preparation when extracted by the method approved by the Licensing Authority under this Part.

(2) When the preparation is a solution of a separated active principle, the unit employed indicating the strength shall be the amount of that active principle yielded to extraction by 0.5 mgm. of the standard preparation as determined by the appropriate biological test.

4. *Quality*—The acidity of the prepared watery extract shall be such that the hydrogen-ion concentration is not less than that corresponding to $pH=4$, or greater than that corresponding to $pH=3$.

5. *Tests*—(1) The method used for preparing the extract from the standard preparation and for its use in a comparative biological test and the biological methods employed in making the test shall be such as the Licensing Authority may from time to time approve.

(2) Samples from each batch of the finished product shall be tested for sterility in accordance with the methods set forth in Part X of the Rules unless the finished product has been sterilized by heat in a manner satisfactory to the Licensing Authority after being sealed in the containers.

6. *Container*—The glass for the container shall be non-alkaline resistance glass.

7. *Labelling*—The label on the container shall indicate the strength of the extract as the number of units per c.c.

8. The date to be specified in compliance with the requirements of Rule 109(1)(c) shall be such date as the Licensing Authority shall in any particular case have approved in writing.

*PART VIII—ADRENALINE INJECTION

1. *Proper Name*—The proper name of the preparation shall be "Adrenaline Injection".

2. *Description*—Adrenaline Injection is a sterile solution of adrenaline in water for injection containing in each 100 ml. 0.08 g. tartaric acid, 0.8 g. Sodium Chloride and not less than 0.09 g. and not more than 0.110 g. of Adrenaline, $C_9H_{13}O_3N$.

3. *Standard Preparation*—The standard preparation is a quantity of pure 1-Adrenaline which complies with the following tests :—

Tests for identity and purity—(1) It gradually darkens on exposure to air. It combines with acids, forming salts which are soluble in water, and from this solution, the base may be precipitated by the addition of dilute solution of ammonia or by alkali carbonates.

(2) It is very slightly soluble in water and in dehydrated alcohol; more soluble in boiling water, practically insoluble in alcohol (90 per cent), ether, in chloroform, in acetone, and in fixed and volatile oils.

(3) It is not stable in neutral or alkaline solution which rapidly becomes red on exposure to air.

(4) Dilute 1 ml. or 0.1 per cent w/v solution in water with 4 ml. of water and add 1 drop of a 10.0 per cent w/v solution of ferric chloride in water; an emerald—green colour is immediately produced which becomes cherry red on the addition of 4 drops of solution of dilute ammonia (Indian Pharmacopoeia).

(5) Add 1 ml. of 0.1 per cent w/v solution in water to 5 ml. of a 10.0 per cent. w/v solution of sodium acetate in water, and add 2 drops of test solution of mercuric chloride (Indian Pharmacopoeia), a red colouration slowly appears which reaches its greatest depth of intensity after half an hour. When the tube is placed for not more than 10 to 15 seconds in boiling water-bath the colour appears more quickly.

Specific rotation—Determined at 25°C in a 4.0 per cent w/v solution in a mixture of 1 volume of hydrochloric acid and 9 volumes of water—50.0° to 53.5°.

Adrenaline—0.05 g dissolves completely in a mixture of 0.15 ml. of water and 0.15 ml. of acetic acid.

Loss on drying—When dried to constant weight at 100° in vacuo, loses, not more than 1.0 per cent of its weight.

Residue on ignition—Not more than 0.1 per cent.

4. *Test for potency*—A suitable solution of adrenaline injected intravenously into a cat or a dog by the methods below produces a rise in the systolic blood pressure of the animal corresponding to that produced by an equal amount of a solution of standard chemically pure adrenaline.

*Amended under Government of India Notification No. F. 1-60.61-D, dated 12th 1962.

Preparation of the solution for the test—The following method is suggested :

Weigh accurately about 0.050 g. of standard adrenaline, dissolve it in 5 ml. of N/1 Hydrochloric acid and dilute this to 50 ml. by the addition of distilled water, thus making a 1 in 1000 solution. The solution must be recently prepared otherwise it deteriorates. It will keep for a short time if preserved in hard glass containers in a refrigerator, but it must be discarded if any signs of deterioration, such as colouration, are observed.

Suitable dilutions of the standard adrenaline solution may then be made in physiological saline for comparison with equivalent dilutions of adrenaline injection to be tested.

Methods of comparison of potency—The following methods of assay are suggested :—

- (a) For the purpose of the assay a full grown cat, preferably male, should be used. The cat should be anaesthetised with a suitable anaesthetic, the spinal cord should be divided and the brain destroyed, the respiration being maintained artificially. The blood pressure is estimated by inserting a cannula into the carotid artery and connecting the same with a mercury manometer which records on a moving drum. The injections are made into the exposed femoral vein. The blood pressure must be low and must not vary before experiments are started. The amount of standard solution necessary to cause a sub-maximal rise in blood pressure by injecting intravenously varying doses of the solution at regular intervals should be determined and after a satisfactory dose has been ascertained the uniformity of reactions should be tested by the injection of two or more doses of equal size. If these injections produce approximately equal increases in blood-pressure alternate injections of the solution to be tested and of the standard are made, varying the amount of the unknown until two or more successive injections raise the blood pressure to the same height, indicating that the amount of active agent is the same in the doses used. From the result thus obtained the strength of the unknown solutions may be determined and adjusted.
- (b) For the purpose of the assay, a dog of medium size should be used. The animal should be anaesthetized with a suitable anaesthetic and maintained under artificial respiration. It is prepared for blood pressure estimations by inserting a cannula into the carotid artery and connecting the same with a mercury manometer which records on a moving drum. The injections are made into the exposed femoral vein. Before the test is made, if in case any muscular movement such as twitching is present, the dog should receive by intravenous injections a sufficient dose of curare, but if the animal is deeply anaesthetised, this is not necessary. The dog should also receive a sufficient dose of atropine sulphate (from 0.001 g. to 0.002 g. per kg. of the dog's weight) to paralyse the vagi, this paralysis being proved by electrical stimulation. Injections must be made at regular intervals of approximately five minutes.

Determine the amount of standard solution necessary to cause a rise in blood pressure from 30 to 60 mm of mercury by injecting intravenously varying dose of the solution and after a satisfactory dose has been ascertained, the uniformity of reaction should be tested by the injection of two or more doses of equal size. If these injections produce approximately equal increases in blood pressure, alternate injections of the solution to be tested and of the standard are made varying the amount of the unknown until two or more successive injections raise the blood pressure to the same height indicating that the amount of active agent is the same in the doses used. From the results thus obtained the strength of the unknown solution may be determined and adjusted.

5. *Containers*—(1) Ampoules shall be made of resistant glass that passes the tests for limits of alkalinity of glass as laid down in the Indian Pharmacopoeia. Containers other than ampoules shall be made of amber coloured resistant glass that passes the test for limit of alkalinity of glass as laid down in the Indian Pharmacopoeia.

(2) The drug shall be made up only in single dose containers of 0.5 ml. or 1 ml. capacity.

(3) The anti-oxidant or preservative which may be added to the solution need not be specified in the formula.

6. *Storage*—Adrenaline Injection shall be kept in ampoules protected from light. If the solution becomes brown in colour or contains a precipitate, it must be rejected. A suitable preservative may be added to the solution.

Labelling—The label of the containers shall contain the following in addition to any other particulars prescribed in these rules :—

1. Strength of the solution.
2. The word 'Sterile'.
3. Dose (0.12 to 0.5 ml. by injection).
4. Date of manufacture and date of expiry, the intervening period must not exceed twelve months.
5. The name and strength of any preservative or antioxidant added shall be shown either on the label of the container or on the package in which the container is enclosed for sale.
6. *Caution*—If the solution is brown in colour or contains a precipitate it must be rejected.

@PART IX—ANY OTHER PREPARATIONS INCLUDING WATER FOR INJECTION IN A FORM TO BE ADMINISTERED PARENTERALLY

1. *Tests*—The preparation shall be in a container which precludes the access of bacteria.

2. The composition of the preparation shall be in accordance with the composition stated on the label. Such deviations as may be allowed in the composition of the preparation shall be fixed by the Licensing Authority.

@ Amended by Govt. of India, Ministry of Health, F.P., & U.D. Notification No. F. 1-14/68-D, dated 26-10-1968.

3. The preparation shall comply with tests for sterility.

*3A. The water used in the manufacture of parenteral preparations shall comply with the tests for pyrogens.

4. If the container is made of glass, the glass shall pass the tests for limit of alkalinity in glass laid down in the Indian Pharmacopoeia.

†Liver Injection Crude

1. Liver Injection Crude is a sterile solution in water for injection of that soluble thermostable fraction of mammalian livers which increases the red blood corpuscles in the blood of persons suffering from pernicious and other types of macrocytic anaemias. It is obtained by stopping the processes of extraction at such a stage that the final product is derived directly from an alcohol solution of a concentration not higher than 70 per cent, by volume, of C_2H_5OH .

Each ml. of Liver Injection Crude has Vitamin B_{12} activity equivalent to either 1 microgram or 2 micrograms of cyanocobalamin. The preparation shall contain not more than 0.5 per cent of cresol or of phenol as a bacteriostatic agent.

2. *Proper name*—The proper name of the preparation shall be Liver Injection Crude.

3. *Description*—A brownish liquid which at times may show a slight turbidity.

4. *Tests*—

(a) *Reaction*—pH 5 to 7.

(b) *Total Solids*—Evaporate to dryness in a water bath, dry at $105^{\circ}C$ for an hour and then at $60^{\circ}C$ in vacuum for 2 hours; cool in a desiccator and weigh. The total solids shall not be less than 15 per cent w/v in the case of preparation containing 2 micrograms of cyanocobalamin per ml. and 7.5 per cent w/v in the case of preparation containing 1 microgram of cyanocobalamin per ml. respectively.

(c) *Limits for proteins*—The protein nitrogen shall not exceed 0.08 per cent w/v as determined by precipitating the proteins with an equal volume of 20 per cent. trichloroacetic acid washing the precipitate with 10 per cent trichloroacetic acid and by estimating the nitrogen content of the precipitate by the Micro-Kjeldahl method.

(d) *Absence of undue toxicity*—The test should be performed on a batch of 5 healthy white mice weighing between 17 and 22 g. Intraperitoneal injection of the sample in dosage of 0.25 ml. per 20 g. of body weight shall not cause death within a period of 120 hours of any of the 5 mice tested. If even one of the 5 mice dies, the test shall be repeated and if there is no mortality in the second batch within a period of 120 hours the sample shall be deemed to have passed the test.

*Amended by Govt. of India, Notification No. F. 1-27/56-D, dated 8-12-1956 and No. F. 1-19/59-D, dated 13-6-1961.

†Added under Government of India Notification No. F. 1-45/58-D, dated 4-1-1961.

* (e) *Sterility test*—Liver Injection Crude shall comply with the sterility test laid down for 'Injection' in the edition of the Indian Pharmacopoeia for the time being.

* (f) *Potency*—The potency shall be determined by the microbiological method for the estimation of vitamin B₁₂ activity as specified in the edition of the Indian Pharmacopoeia for the time being and shall be not less than that stated on the label.

5. *Container*—The container used for Liver Injection Crude shall comply with the requirements laid down in the Indian Pharmacopoeia for container of 'Injections'.

6. *Storage*—Liver Injection Crude shall be stored in a cool place preferably at a temperature not exceeding 20°C, and protected from light.

7. *Label*—The label on the container shall state the following details in addition to any other particulars prescribed in these Rules :—

- (1) The amount of Vitamin B₁₂ activity (Cyanocobalamin) per ml.
- (2) The average amount of raw liver processed to produce 1 ml. of the extract.
- (3) The date of expiration of potency which should not be later than 24 months from the date of manufacture, and
- (4) The name and quantity of the bacteriostatic agent added.

PART X—SURGICAL LIGATURE AND SURGICAL SUTURE

1. *Proper Name*—Surgical ligature or suture is any ligature or form of binding material of animal, vegetable or synthetic origin and offered or intended to be offered for sale for use in surgical operation upon the human body. Where such ligature or suture is offered or intended to be offered for sale as sterile and ready for use the proper name of substance shall be "sterilized surgical ligature" or "sterilized surgical suture" followed, in brackets, by the accepted scientific name or a title descriptive of the true nature and origin of the substance as for example—"Sterilized Surgical Ligature (catgut)" or "Sterilized Surgical Suture (horsehair)."

2. *Test for sterility*—Every batch of surgical ligature (suture) shall consist entirely of material collected under uniform conditions and simultaneously subjected or intended to be subjected to the same process or series of processes for rendering it sterile.

3. A sample of surgical ligature (suture) shall be taken from each batch consisting of not less than 1 per cent. of the whole quantity of material constituting the batch. The sample shall, when practicable, be the contents of at least one whole container or packet, and shall be drawn at random from the whole number of containers or packets constituting the batch.

4. The sample shall be subjected to the following process for testing sterility.

*Amended by S.O. No. 2139 dated 12-8-1972 (Government of India Notification No. 11014/12/72-D, dated the 5th June 1972)

- (a) the container or packet shall be opened and the sample removed with aseptic precautions;
- (b) after all the adherent fluid has been drained off as completely as possible the sample shall be placed entire in a test tube at least 3.5 cm. in diameter 17.5 cm. in length and containing 50 ml. of sterile distilled water. This tube shall then be closed by some method which will preclude the access of bacteria and be placed in incubator at 37°C for 24 hours;
- (c) after this incubation, the sample shall be aseptically transferred to a similar tube containing a solution of 1 per cent of sodium thiosulphate and 1 per cent of crystallized sodium carbonate in distilled water, the tube and solution having been previously sterilized in autoclave. In this solution the sample shall again be incubated for 24 hours at 37°C.
- (d) after the second incubation the sample shall be again removed aseptically and, without further washing, shall be examined for the presence of living bacteria and their spores.

The sterility tests shall be carried out either (i) by the method prescribed in Rules 117 (1), (2), (3), and 118 (1) or (2) by placing the sample in a tube at least 3.5 cm. in diameter and 17.5 cm. in length containing not less than 50 ml. of a culture medium prepared by dissolving 0.2 per cent of prepared agar-agar in a nutrient bacteriological broth* the mixture being sterilized in the autoclave :

Provided that, if manufacturer satisfies the Licensing Authority that he has already in use tests for the presence of living aerobic or anaerobic bacteria and that these tests, as applied by him, will detect the presence of such bacteria in the ligature (suture) as ready for issue with a certainty at least equal to that afforded by the application of the tests prescribed in the above mentioned articles the Licensing Authority may approve the use of such test in the place of the tests so prescribed; but, in that event, the authority may at any time withdraw such approval and require the manufacturer to carry out the prescribed tests;

- (e) the tubes of culture medium containing the sample shall be incubated at 37°C for 12 days, and examined daily for the growth of bacteria;
- (f) if no such growth is detected during this period, the batch from which the sample was drawn shall be treated as free from living bacteria and their spores, and as having passed the test :

Provided that, if a licensee satisfies the Licensing Authority that the tests prescribed in sub-paragraph (c) of this paragraph for freeing substances from combined or adherent antiseptics are not suitable for application to the substance which he is licensed to manufacture or import, the Licensing Authority may approve in writing the application of alternative tests in place of the tests so prescribed.

Labelling—For the purpose of Rule 109(1)(c) the date on which the manufacture of the batch is completed shall be the date on which the test for sterility was completed.

*Note.—The broth may preferably be made by the digestion of meat with trypsin Doughal's broth or Hartly's modification thereof.

***PART XI—PROVISIONS APPLICABLE TO THE PRODUCTION OF
BACTERIOPHAGES**

1. *Definition*—(i) This part of this Schedule applies to the bacteriophages made from any micro-organism pathogenic to man or other animal.

(ii) For the purpose of this Part of this Schedule a bacteriophage means a sterile preparation derived from a culture of the micro-organism from which the bacteriophage derives its name.

2. *Staff of establishment*—Any establishment where bacteriophages are prepared must be under the complete direction and control of a competent expert in bacteriology, who must be assisted by a staff adequate for carrying out the tests required during the preparation of the bacteriophages and in connection with the finished products.

3. *Proper name*—The proper name of any bacteriophage shall be the word 'Bacteriophage' followed by the name of the Micro-organism from which it is prepared, or other name approved by the Licensing Authority.

4. *Records*—Cultures used in the preparation of bacteriophages must before being manipulated into a bacteriophage be identified by the generally accepted tests applicable to the particular micro-organism. The permanent records which the licensee is required to keep shall include a record of the origin, properties and characteristics of the cultures.

5. *Combined bacteriophages*—Bacteriophages may be issued either singly or combined in the same container. In the case of combination of bacteriophage a name for the combined bacteriophage may be submitted by the licensee to the Licensing Authority, if approved, may be used as a proper name of the bacteriophage.

6. *Containers*—The container shall be sealed glass ampoule of non-alkaline resistance glass.

7. *Labelling*—The label of the container shall indicate :—

- (a) the proper name of the bacteriophage;
- (b) the words 'For oral administration only';
- (c) the date of manufacture; and
- (d) a caution to the effect that if the preparation is cloudy or shows a deposit it should be discarded.

8. *Tests*—Bacteriophages shall be subjected to the same tests for sterility as prescribed in these Rules for bacterial vaccines.

**†PART XII—(A) THE DIGITALIS GROUP OF DRUGS AND ERGOT AND ITS
DERIVATIVES**

1. *Proper names, etc*—The proper names, standard preparations, units of standardization, quality and method of storage of drugs belonging to the digitalis group and of ergot and its derivatives shall be those specified in the Indian Pharmacopoeia.

*Amended under Government of India Notification No. F. 18-1/46-D, dated 18-6-1948.

†Amended by Government of India Notification No. F. 1-63-61/D, dated 17th July, 1963.

2. *Tests*—Drugs belonging to the digitalis group and ergot and its derivatives shall be submitted to the tests described in the Indian Pharmacopoeia.

(B) FISH-LIVER OILS

1. *Units of standardization*—The units of standardization for vitamin preparations shall be those specified in the Indian Pharmacopoeia.

2. *Tests*—Fish-liver oils and other vitamin preparations shall be submitted to one of the tests for activity specified in the Indian Pharmacopoeia.

(C) LIQUOR ADRENALINAE HYDROCHLORIDE NOT TO BE ADMINISTERED PARENTERALLY

These preparations shall be submitted to the test prescribed in Part VIII of this Schedule except that they will not be tested for sterility. The label on the container and the label or wrapper on the package shall bear the words "Not to be injected" clearly printed in a distinctive manner in addition to any particulars prescribed in these Rules.

(D) PREPARATIONS CONTAINING ANY VITAMINS IN A FORM NOT TO BE ADMINISTERED PARENTERALLY

1. *Definition*—Vitamins include natural and synthetic Vitamins, synthetic derivatives of Vitamins, Vitamin esters and synthetic substances having physiological actions comparable with those of the aforementioned substances and natural products containing Vitamins.

2. *Units of standardization*—The units of standardization for Vitamin preparations shall be those specified in the Indian Pharmacopoeia.

3. *Tests*—Drugs containing Vitamins shall be submitted to the tests for Vitamins prescribed in the Indian Pharmacopoeia.

4. *Labelling*—(1) The number of units and/or the actual weight of each vitamin per unit volume and/or weight shall be declared on the label.

‡(2) Omitted.

*(E) STANDARDS FOR PREPARATIONS OF LIVER FOR ORAL USE

1. *Desiccated Liver*—(*Desiccated Liver Substance*)—Desiccated Liver is the dried, defatted or underfatted powder prepared from mammalian livers suitable for use as food by man. Each gram of Desiccated Liver contains the equivalent of not less than 2 mcg. of cyanocobalamin; it contains not less than 10 per cent of nitrogen.

Desiccated Liver is prepared from sound, clean and entire glands that are free from external connective tissue and external fat, and dried in a vacuum at a temperature not exceeding 60°C. It is free from diluents or preservatives. One part of Desiccated Liver is obtained from approximately 4 parts, by weight, of fresh glands.

2. *Liver Concentrate*—Liver Concentrate is the dried, unfractionated product resulting from the water or acidified water extract derived from

‡Omitted under Government of India Notification No. F. 1-23/51-D, dated 9-2-1958.

*Amended by Government of India Notification No. F. 1-63/61-D, dated 7th July 1962.

mammalian livers suitable for use as food by man. Each gram of liver concentrate is derived from not less than 15 grams of fresh liver and contains not less than the equivalent of 7.5 mcg. of cyanocobalamin; it contains not less than 9 per cent of nitrogen.

Liver Concentrate is prepared from finely minced fresh or frozen livers by extraction with water, with or without the addition of acid. The protein is coagulated by heat, the insoluble material removed, and the solution is concentrated and dried in vacuum or a spray dryer.

Liver Concentrate shall not be subjected to any fractionation process, such as those involving solvents or absorbents, and it does not contain added diluents other than an amount, not to exceed 5 per cent of a harmless substance to prevent caking.

Liver Concentrate may also be used in the form of a paste with a solid content not less than 65 per cent W/W, but the labelling should be on dry basis, the specification being the same as given above. **It may contain 0.1 percent of benzoic acid or a suitable concentration of other harmless preservatives.

3. *Liver Fraction 1. (Soluble Liver Fraction)*—Liver Fraction 1 is the product in paste form, containing that portion of liver concentrate soluble in 70 per cent. alcohol, and free from diluents. Each gram of Liver Fraction 1 is derived from not less than 25 grams of fresh liver and contains the equivalent of not less than 6 mcg. of cyanocobalamin. It contains not less than 6 per cent. of nitrogen. It may contain 0.1 per cent. of benzoic acid or a suitable concentration of other harmless preservative.

4. *Liver Fraction 2. (Insoluble Liver Fraction)*.—Liver Fraction 2 is a product containing that portion of liver concentrate insoluble in 70 per cent. alcohol. It does not contain added diluents or preservatives other than an amount not to exceed 5 per cent. of a harmless substance to prevent caking. Each gram of Liver Fraction 2 is derived from not less than 25 grams of fresh liver; it contains not less than 6 per cent. of nitrogen.

5. *Proteolysed Liver*—Proteolysed Liver is a mixture of the products of digestion of edible mammalian livers, and may be prepared by digesting mammalian liver with a proteolytic enzyme at a temperature of 50° to 60° and at pH of 5 to 6. The product is heated at 100° for 5 minutes to inactivate the enzyme, filtered, concentrated under reduced pressure, and evaporated to dryness in vacuum or a spray dryer.

It may contain up to 5 per cent of a harmless substance added to prevent caking.

Each gram of Proteolysed Liver is derived from not less than 6 grams of fresh liver and contains the equivalent of not less than 4 mcg. of cyanocobalamin; it contains not less than 11 per cent. of nitrogen.

Amino-acid content—This test should be the same as in the Indian Pharmacopoeia, but substituting the words "decolourised with activated charcoal and adjusted to pH 7" for the words "adjusted to pH 7". This change is suggested because Proteolysed Liver solution is dark-brown in colour and decolourisation helps in obtaining a clear end-point in the formal titration.

**Added by S. O. No. 2139, dated 12-8-1972. (Govt. of India Notification No. X-11014/12/72-D, dated the 5th June, 1972).

Proteolysed Liver may also be used in the form of a paste, with a solid content not less than 65 per cent W/W, but the labelling should be on dry basis, the specifications being the same as given above. It may contain 0.1 per cent. of benzoic acid or a suitable concentration of other harmless preservative.

****MANNER OF LABELLING—PREPARATIONS OF LIVER FOR ORAL USE**

Subject to the other provisions of these rules and this Schedule a preparation of Liver for oral use for which standards have been laid-down in this Part of Schedule shall bear on the label the name of the preparation as prescribed.

In case the preparation of Liver for Oral use is presented as a paste, the word 'paste' shall be added after the name prescribed and the solid content, weight/weight, shall also be stated on the label.

In case any patent or proprietary preparation contains one or more of the preparations of Liver for Oral Use prescribed above, the formula of such a patent or proprietary preparation shall show the name or names, as the case may be, of the preparation or preparations prescribed in this Part and the quantity which shall be expressed on dry basis when the paste is used.

(F) PREPARATION CONTAINING HORMONES IN ANY FORM NOT TO BE ADMINISTERED PARENTERALLY

1. *Definition*—Hormones include natural and synthetic Hormones, synthetic derivatives of Hormones, Hormones esters and synthetic sub-blandular products containing Hormones.

2. *Tests*.—Drugs containing Hormones shall be submitted to tests prescribed in the Indian Pharmacopoeia or as directed by the Licensing Authority if any particular Hormone is not included in the Indian Pharmacopoeia.

***3. Omitted.**

†PART XII-A—PROVISIONS APPLICABLE TO ANTIBIOTICS AND THEIR PREPARATIONS

Injection of Procaine Benzyl Penicillin in Oil with Aluminium Stearate Suspension

Injection of Procaine Benzyl Penicillin in Oil with Aluminium Stearate Suspension is a sterile suspension of procaine benzyl penicillin in a suitable oil containing 2 per cent w/v of aluminium monostearate. It contains not less than 90 per cent of the number of International Units of Penicillin stated on the label.

Proper name—The proper name shall be "Injection of Procaine Benzyl Penicillin in Oil with Aluminium Stearate Suspension" or "Sterile Procaine Penicillin G with Aluminium Stearate Suspension".

**Added by S.O. No. 2139 dated 12-8-1972 (Government of India Notification No. X. 11014/12/72-D, dated the 5th June, 1972).

*Omitted under Government of India Notification No. F. 1-23/51-D.S., dated 9-2-1958.

†Added under Government of India Notification No. F. 1-22/59-D, dated 9-4-1960.

Consistence—Passes readily through a hypodermic needle of internal diameter 0.905 mm. at 25°C.

Particle Size—The diameter of not less than 65 per cent of the particles does not exceed 5 microns.

Stability—When shaken by hand it forms a suspension which is stable for 48 hours at 37°C; if any separation takes place during this time, the thickness of the oily layer should not be greater than 3 mm.

Water—Not more than 1.4 per cent.

Sterility—After the addition of a quantity of solution of penicillinase or other suitable inactivating agent adequate to ensure complete inactivation of the penicillin present, complies with the test for sterility.

Blood-level duration—When determined as described in the Appendix, a quantity equivalent to 3,00,000 International Units of penicillin produces blood-serum levels at 72 hours of not less than 0.03 International Units per ml. in not less than half the number of subjects used.

Other requirements—Complies with the requirements stated under “Injections” in the Indian Pharmacopoeia.

Assay—The potency is determined by the method included in the Appendix.

Storage—Injection of Procaine Benzyl Penicillin in Oil with Aluminium Stearate Suspension should be stored in a cool place, but not in a refrigerator.

Labelling—The label on the container must state (1) the name of the injection; (2) the number of International Units in 1 ml.; (3) “For intramuscular use only”.

When Injection of Procaine Benzyl Penicillin in Oil with Aluminium Stearate Suspension is prescribed, no strength being stated, the injection containing 3,00,000 International Units per ml. shall be dispensed.

APPENDIX

BLOOD LEVEL DURATION TEST

1. *The Test*—Ten or more persons in good health and weighing between 60 and 90 kg. who have not taken penicillin or similar antibiotics in any form during the previous seven days are selected as test subjects. Each subject is injected with a quantity of the Injection of Procaine Benzyl Penicillin in Oil with Aluminium Stearate Suspension under test equivalent to 3,00,000 International Units of penicillin. A 5 ml. sample of venous blood is withdrawn 72 hours after the injection and if desirable, at other times during the test period; the subject should receive no other antibiotic during this period. The blood is allowed to clot and the serum is separated by centrifuging and transferred immediately to sterile tubes. If it is not to be tested on the same day, the serum is frozen at -20°C or below and stored frozen. The penicillin content of the samples of serum is determined as described below :—

The Blood-serum Assay (Sarcina Lutea Method)

The antibiotic potency of a sample of serum presumed to contain penicillin is determined by comparing the volumes of it required to inhibit the growth of a standard strain of *Sarcina Lutea* with the quantities of a standard preparation of penicillin required to produce the same degrees of inhibition.

Working Standard Solution

To about 0.015 g. of the International Standard preparation of penicillin, accurately weighed in an atmosphere of 50 per cent relative humidity or less, sterile 1 per cent phosphate buffer, pH 6.0 is added to make a stock solution containing 0.6 mg. per ml. (1,000 International Units per ml). This solution is kept at a temperature of about 10°C and used for two days only. On the day of the assay, this stock solution is diluted to 1.0 International Units per ml. using the above mentioned buffer. Working dilutions of the latter solution are prepared using as the diluent bovine albumin TS which, before use, has been filtered through a bacteria-proof filter and tested on plates for inhibition of *Sarcina Lutea* under the conditions outlined below. Bovine albumin TS which shows inhibition under these conditions should not be used.

Preparations of serum samples

Serum samples expected to contain not more than 0.4 International Unit per ml. need not be diluted. Samples expected to have a potency greater than 0.4 International Unit per ml. should be diluted to about 0.1 International Unit per ml. with bovine albumin TS known to have no antibiotic activity.

Suggested Method

The general procedure described under "Biological Assay of penicillin" is applied with the specific changes set forth below.

Media :

Nutrient agar for the base layer and for carrying the test organism is prepared as follows :—

Peptone	6.0 g.
Pancreatic Casein digest	4.0 g.
Yeast Extract	3.0 g.
Beef Extract	1.5 g.
Glucose	1.0 g.
Agar	15.0 g.
Water, sufficient to produce	1,000 ml.

The media is adjusted so that the pH is 6.5 to 6.5 after autoclaving at 121°C for 20 minutes.

Agar for the inoculated layer is prepared as above, but omitting the pancreatic digest of casein and adjusting the reaction so that the pH is 6.5 to 6.6 after autoclaving.

Nutrient broth for preparing an inoculum of test organism is prepared as follows :—

Peptone	5.0 g.
Yeast Extract	1.5 g.
Beef Extract	1.5 g.
Sodium Chloride	3.5 g.
Glucose	1.5 g.
Dibasic Potassium Phosphate	3.68 g.
Potassium Dihydrogen Phosphate	1.32 g.
Water, sufficient to produce	1,000 ml.

The media is adjusted so that the pH is 6.9 to 7.0 after autoclaving.

Instead of preparing the media from the individual ingredients specified they may be prepared from a dehydrated mixture which when reconstituted with water, has the specified composition. Minor modifications of the individual ingredients specified are permissible if the resulting media possess growth promoting properties at least equal to the media described.

Preparation of Bulk Culture Suspension

The test organism is *Sarcina Lutea* (P.C.I., 1001 and American Type Culture Collection 9341). The test organism is maintained on slants of nutrient agar as described for the base layer and transferred to a fresh agar slant once a week. A suspension of the test organism is prepared as follows. An agar slant is streaked heavily with the test organism and incubated for 24 hours at 26°C. The growth is washed off with 3.0 ml. of nutrient broth. The suspension so obtained is used to inoculate the surface of a Roux bottle containing 300 ml. of this nutrient agar. The suspension is spread over the entire surface with the aid of sterile glass-beads. The bottle is incubated for 24 hours at 26°C. Growth is washed from the agar surface with 15 ml. of nutrient broth prepared as described. The density of organisms in this bulk suspension is tested by diluting 1 part with 9 parts of nutrient broth, and measuring the light transmission at about 650 mu. in a suitable photoelectric colorimeter. If the light transmission is about 10

per cent of that of sterile nutrient broth similarly treated, the bulk suspension is satisfactory for use. Otherwise, the bulk suspension is adjusted by dilution so that a 10 per cent dilution of the adjusted suspension gives about 10 per cent light transmission. The bulk suspension, adjusted by dilution if necessary, may be used for at least two weeks.

Preparation of plates

On the day of the assay 10 ml. of base layer agar-medium is added to Petri plates (20 mm. \times 100 mm.). The agar is distributed evenly in the plates and allowed to harden.

0.4 ml. of bulk culture suspension is added to 100 ml. of the agar prepared for the inoculated layer, previously melted and cooled to 48°C. The culture and agar are thoroughly mixed and 4 ml. are added to each of the plates containing the 10 ml. of the hardened uninoculated agar. The inoculated agar is spread evenly over the surface by tilting the plates back and forth. The plates are covered with porcelain covers, glazed on the outside.

Standard curve and assay procedure

Six cylinders are placed on the inoculated agar surface so that they are at approximately 60° intervals on a 2.8 cm. radius. One plate is used for each sample. Three cylinders on each plate are filled with the 0.1 ml. International Unit per ml. dilution of the International Standard Preparation, and three cylinders with the serum sample under test, alternating Standard and sample. The plates are incubated for 16 to 18 hours, at 26°C and the diameter of each zone of inhibition is measured. At the same time, a standard curve is prepared using concentrations of 0.03, 0.05, 0.10, 0.20, 0.30 and 0.40 International Units per ml. of the International Standard Preparation in bovine albumin TS. Three plates are used for the determination of each point on the curve making a total of 15 plates. On each of three plates, three cylinders are filled with the 0.1 International Unit per ml. dilution of the International Standard Preparation and the other three are filled with one of the five other diluted solutions of the International Standard Preparation. After the plates have been incubated the diameters of the zones of inhibition are read. Thus, there will be 45 determinations at 0.1 International Unit and nine determinations at each of the other points on the curve.

The readings of 0.1 International Unit per ml. concentrations and the readings of the point tested for each set of three plates are averaged and also all 45 readings of the 0.1 International Unit per ml. concentration. The average of the 45 readings of the 0.1 International Unit per ml. concentration is the correction point for the curve. The average value obtained for each point is corrected to the figure it would be of the 0.1 International Unit per ml. readings for that set of three plates were the same as the correction point. Thus, if the average of the 45 readings of the 0.1 International Unit concentration is 20.0 mm., and the average of 0.1 International Unit concentration of a given set of three plates is 19.8 mm. correction is +0.2 mm. If the average reading of the 0.5 International Unit concentration of these same three plates is 17.00 mm., the corrected value, becomes 17.2 mm. The corrected value, including the average of the 0.1 International Unit per ml. concentration, are plotted on 2 cycle semi-logarithmic graph paper using the concentration in international units per ml. as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the

abscissa. The standard curve is drawn through these points. To estimate the concentration of penicillin in the sample, the zone readings of the International standard and the zone readings of the sample on the plate used are averaged. If the sample gives a large average zone size than the average of the International Standard the difference between the two averages is added to the 0.1 International Unit zone on the standard curve. If the average sample value is lower than the standard value, the difference between the averages is subtracted from the 0.1 International Unit value on the curve. From the curve are read the concentrations of Penicillin in International Units per ml. corresponding to these corrected average zone sizes.

The reagents and solutions refer to the reagents and solutions included in the Indian Pharmacopoeia.

†PART XII-B

EQUIPMENT AND SUPPLIES REQUIRED FOR A BLOOD BANK

Blood Donor Room

A. *Equipment :*

The blood donor room shall be air conditioned.

1. *Donor beds or tables :* The top of the bed or the table shall be padded with heavy felt or foam rubber and shall be covered with a washable plastic material. The top of the bed or the table shall be sufficiently wide to give support to the arm of the donor. The table shall also be suitable to the requirements besides being comfortable.

2. Bed side stand.

3. Shaking apparatus or apparatus for mixing blood by technical staff.

4. Sphygmomanometer and stethoscope.

5. Recovery bed of about 50 cm. in height.

6. *Accessory item :* Such as blankets, emesis basins, hemostats, donor set clamps, sponge forceps, dressing jars, solution jars, waste cans and adjustable lamps.

B. *Blood collection supplies :*

The blood collection shall be done either by the closed method or by the gravity methods. Donor sets with 16 S.W.G. 5 cm needles, donor bottles (Pyrogen free), lancets for haemoglobin and pilot tubes shall be sterile and ready for being used. The needles shall be piercing needles made of stainless steel gauge 11 x 16 cm or 26 cm. length depending upon the size of the bottle. When the gravity method is used the outlet needles must have a sterile cotton wool filter.

1. *Haemoglobin determination :*

(a) Copper sulphate solution, specific gravity 1.052.

(b) Sterile lancets.

(c) Capillary tubing 1.3—1.4 x 65 mm or pasteur pipettes.

(d) Rubber bulbs for capillary tubings.

(e) Sahli's Haemoglobinometer.

†Added under Govt. of India, Ministry of Health, F.P., W.H and U.D. Notification No. F. 1—17/67-D dated 24-6-67.

2. *Temperature and pulse determination :*

- (a) Clinical thermometers.
- (b) Equipment and material for aseptic cleaning the thermometer.
- (c) Watch (fitted with a second hand needle).
3. Blood collection bottles—375 ml.
4. Blood collection sets.
5. Sterile pilot tubes for being attached to the flow bottle.
6. Hypodermic syringes 2 ml. needle of 26 s. w. g./1.5 cm.
7. Cotton gauze squares (5 cm \times 5 cm), medium cotton balls, 1.25 cm adhesive tape.
8. Alcohol (70 per cent), greensoap or liquid soap; Tincture Iodine and Injection of Procaine.
9. Paper napkins or towels.

C. *Canteen equipment :*

Provision for serving refreshments to the donor after phlebotomy may also be made so that he may be kept for observation in the blood bank for any reactions.

D. *Emergency equipment :*

1. Small Oxygen cylinder with mask, gauge and pressure regulator.
2. Plasma and/or albumin (Human).
3. Sterile syringe and needle.
4. Sterile I. V. Infusion set.
5. Ampoules of Adrenaline, Injection of Calcium Gluconate, Injection of Atropine, Injection of Nikethamide and Injection of Nor-adrenaline, Distilled water.
6. Aspirin and Aromatic Water.

LABORATORY

A. *Equipment :*

1. Refrigerators maintaining a temperature between 4° to 6°C, with as little deviation as possible in temperature.
2. Alarm system for alerting a person on duty in event of very high deviation in temperature or failure of the machine.
3. Recording thermometer for refrigerator.
4. Charts and ink for recording thermometer.
5. Microscope, compound with low and high power objectives.
6. Centrifuges—Table model for blood grouping and cross matching.
7. Water baths—one for 37°C and another for 56°C.
8. Rh viewing box. The surface of viewing glass shall not have 'hot spots' and its temperature shall not exceed 47°C.
9. Incubator, bacteriological for control cultures.
10. Mechanical shakers for serological tests for syphilis.

11. Hand lens for observing tests conducted in tubes.
12. Pipettes, serological, 1.0 ml. graduated in .001, .01, 0.2 ml.
13. Pipettes, Pasteur.
14. Glass slides, glass plates and/or porcelain deep wells or plates.
15. Test tubes, serological, 13 × 100 mm.
16. Precipitating tubes 6 mm x 50 mm.
17. Test tube racks.
18. 15 cm. applicators and toothpicks.
19. Interval timer, electric or spring wound.
20. Equipment and materials for cleaning glassware adequately.
21. Shipping containers.

B. Reagents :

1. Standard Blood grouping sera, Anti-A and Anti-B and Anti-AB, all in double quantity and each of a different brand, or if from the same suppliers each supply should be of a different lot number.

2. Rh typing sera. All in double quantity and each of a different brand or if from the same supplier, each supply should be of a different lot number.

3. Reagents for serological tests for syphilis and positive sera for controls.

4. Anti-human globulin serum (Coombs serum) for confirming cross-matches, determining Rh negative blood and performing antibody tests.

5. Albumin, human or bovine, 30% for tests, requiring high protein concentration.

6. 0.9% saline.

7. Culture media and tubes.

8. Wax pencils and labels.

9. Detergents and other agents for cleaning laboratory glassware.

GENERAL SUPPLIES

1. Autoclave.

2. Temperature recorder (The autoclave should be equipped with a temperature recording device which gives a record of temperature and length of time for each sterilization).

TECHNICAL STAFF

1. A medical graduate having experience in blood bank.

2. Registered nurse—one

3. Blood bank technician having experience in blood grouping and serology work.

4. One Assistant.

5. One Attendant.

ACCOMMODATION FOR BLOOD BANK

Minimum total area should be about 100 square Meters and consisting of six rooms, namely :—

1. Registration and medical examination room.
2. Blood Collection room.
3. Room for laboratory.
4. Room for sterilizing and washing.
5. Refreshment room.
6. Room for keeping records and stores.

LABEL FOR WHOLE BLOOD

The label on the blood container should contain the following particulars namely :—

1. The serial number of the bottle.
2. The date on which the blood is drawn, and the date of expiry which shall not be more than 21 days from the date on which the blood is drawn.
3. The ABO group with the corresponding colour.

COLOUR SCHEME FOR LABEL

The following colour scheme for labels may be used for different groups :—

<i>Group</i>	<i>Colour of Label</i>
O	Blue
A	Yellow
B	Pink
AB	White

4. The Rh group.
5. The total volume of fluid, the proportion of blood and the formula and proportion of anticoagulant.
6. The contents should not be used if there is any visible evidence of deterioration.
7. Name of Blood Bank.
8. Address.
9. A filter must be used in administration equipment.
10. Keep continuously at 4° to 6°C.
11. Cross-match before using.

Precautionary Measures :

1. Administer without warming.
2. Shake gently before using.
3. Do not add other medication to the blood.
4. Check blood group on label and recipient's group, before administration.

5. Use a fresh, clean and sterile transfusion set to transfuse the blood.
6. Do not dispense without prescription.

NOTE.—The above requirements of Blood Bank are subject to modifications at the discretion of the Licensing Authority if he is of the opinion that having regard to the extent of the manufacturing operations it is necessary to relax or alter them in the circumstances of a particular case.

*PART XIII—GENERAL

1. For the purposes of this Schedule, any test or method of testing described in the Indian Pharmacopoeia shall be deemed to be a method approved by the Licensing Authority.
2. The Licensing Authority shall publish in the Official Gazette from time to time particulars of any test or method of testing approved by him.

†SCHEDULE F(1)

PART I—VACCINES

(A) PROVISIONS APPLICABLE TO THE PRODUCTION OF BACTERIAL VACCINES

1. *Definition.*—(1) This part of the Schedule applies to bacterial vaccines made from any micro-organism pathogenic to man or other animal and to vaccines made from other micro-organisms which have any antigenic value.

(2) For the purposes of this part of the Schedule, a bacterial vaccine means a sterile suspension of a killed culture of the micro-organism from which the vaccine derives its name or a sterile extract or derivative of a micro-organism, or a pure suspension of living micro-organisms which have been previously made avirulent.

2. *Staff of Establishment.*—A competent expert in bacteriology with sufficient experience in the manufacture and standardisation of biological products shall be in charge of the establishment responsible for the production of bacterial vaccine and he shall be assisted by a staff adequate for carrying out the tests required during the preparation and standardisation of the vaccines.

3. *Proper Name.*—The proper name of any vaccine shall be the name of the micro-organism from which it is made followed by the word "Vaccine" unless this Schedule otherwise provides or if there is no other special provision in this Schedule, some other name as approved by the Licensing Authority. Provided that in the case of the undermentioned preparations the proper name of the vaccine may be as follows :—

1. Anthrax Spore Vaccine (Living)
2. Blackquarter Vaccine.
3. Enterotoxaemia Vaccine.
4. Fowl Cholera Vaccine.

*Renumbered under Government of India Notification No. F. 18-1/46, dated 18-6-48

†Added under Govt. of India, Ministry of Health F.P., W.H. and U.D. Notification No. F.1-6/62-D, dated 2-7-1969.

5. Haemorrhagic Septicaemia Adjuvant Vaccine.

6. Haemorrhagic Septicaemia Vaccine (Broth).

4. *Records*.—Cultures used in the preparation of vaccine before being manipulated into a vaccine, should be thoroughly tested for identity by the generally accepted tests applicable to the particular micro-organisms.

The permanent records which the licensee is required to keep shall include amongst others, a record of the origin, properties and characteristics of the cultures.

5. *Combined Vaccines*.—Vaccines may be issued either singly or combined in any proportion in the same container. In the case of combination of vaccines, a name for the combined vaccine may be submitted by the licensee to the Licensing Authority, and if approved, may be used as the proper name of the vaccine.

6. *Preparation*.—Bacterial vaccines, simple or polyvalent, are prepared from selected cultures after careful examination for their identity, specificity, purity and antigenicity. They may be prepared in the following manner :—

(a) *Formal Cultures or Bacterins*.—The selected pure culture strain or strain are grown in a suitable fluid medium, at an optimum temperature, for an appropriate period. The pure growth is then exposed to the action of solution of Formaldehyde I.P. in suitable concentration and temperature. The product is finally filled in suitable sterilised containers which are subsequently sealed.

(b) *Vaccine of Bacterial Products or Bacterial Derivatives*.—These vaccines are prepared by growing the organisms on suitable media and then deriving specific antigenic constituents of the bacteria by various special methods.

(c) *Living Bacterial Vaccines*.—They are prepared from non-pathogenic but fully immunogenic strains of micro-organism. Strict aseptic precautions are taken throughout the preparation against the introduction of microbial contaminants.

7. *General Standards* :—

(a) *Description*.—Bacterial vaccines are colourless to yellowish brown liquids containing dead or viable bacteria in homogenous suspension.

(b) *Identification*.—All types of vaccines confer active immunity in the susceptible animals which can be demonstrated by injecting suitable experimental animals with the calculated doses of the product and subsequently determining the presence of the protective antibodies in their serum and/or by challenging the vaccinated animals by injecting virulent strain of the homologous organisms. The protected animals should survive the challenge.

(c) *Test for Sterility*.—All bacterial vaccines shall be tested for sterility in accordance with the provision of Rules 115 to 119 (both inclusive). If the vaccine contains added bactericide or bacteriostatic, a quantity of medium sufficient to render the growth inhibitor ineffective is added to the sample, or a suitable substance is added to the sample, or a suitable substance is added in concentration sufficient to render the growth inhibitor ineffective but not itself to inhibit the growth of micro-organism.

(d) *Purity Tests for Living Bacterial Vaccine*—Petri-dishes containing suitable media are streaked with the final product and incubated at 37°C for 72 hours. The vaccine passes the test if no growth of micro-organisms other than those from which the vaccine was prepared is observed. Other tests include examination for motility of the organisms, fermentation reactions and thermoagglutination test and dye-inhibitor tests in case of brucella vaccine.

(e) *Safety Test*—The safety of the vaccine shall be assessed by injecting it in appropriate dose in suitable susceptible animals. No animal should show any untoward, general or local reaction, within seven days after inoculation.

(f) *Potency Test*—Wherever applicable, susceptible experimental animals are inoculated with the calculated doses of the final product. The animals are challenged, after the period of immunisation, with virulent infective dose of the homologous culture along with the controls. The potency of the vaccine is assessed by the survival of the vaccinated animals and the death of the controls.

8. *Labelling* :—

(a) The label on the ampoule or the bottle shall indicate :

- (i) Proper name.
- (ii) Contents in millilitres or doses.
- (iii) Potency, if any.
- (iv) Batch number.
- (v) Expiry date.

(b) The label on the outside container shall indicate :

- (i) Proper name.
- (ii) Contents in millilitres or doses.
- (iii) Batch number.
- (iv) Date of manufacture.
- (v) Manufacturing licence No.
- (vi) Manufacturer's name and address.
- (vii) "For animal treatment only".
- (viii) Storage conditions.

9. *Storage*.—Bacterial vaccines shall be stored, protected from light at temperature between 2°C to 4°C and shall not be frozen.

10. *Date of Manufacture*.—The date of manufacture shall be, unless otherwise specified in the individual monograph in this Part, as defined in clause (b) of sub-rule (3) of rule 109.

Anthrax Spore Vaccine (Living)

1. *Synonyms*.—Avirulent Anthrax Spore Vaccine or Bacillus Anthracis Vaccine (Living).

2. *Definition*.—The vaccine is a suspension of living spores of an un-capsulated avirulent strain of B. anthracis in 50 per cent glycerine saline.

3. *Preparation*.—Avirulent *B. anthracis* of known antigenicity is grown on suitable medium at pH. 7.4 in Roux flasks. After 72 hours incubation at 37°C, the pure sporulated culture growth which shows 70 to 80 per cent sporulation is washed with normal saline and glycerinated to the extent of 50 per cent by weight of the culture washing and the whole suspension is kept at room temperature for twentyone days to allow for the stabilization of the spores.

4. *Standard* :—

(a) *Description*—It is slightly opalescent or pale brown semi-viscous liquid.

(b) *Identification*—Uncapsulated *B. anthracis* which is avirulent can be isolated from the vaccine.

(c) *Sterility test*—Should comply with the test for sterility described in the general monograph on "Bacterial Vaccine".

(d) *Purity Test*—Complies with the "Purity Tests for Living Bacterial Vaccine" described under the general monograph on "Bacterial Vaccines."

(e) *Safety Test*—Four healthy adult guinea-pigs each weighing 300-450 g. not previously treated with any material which will interfere with the test are inoculated subcutaneously, two with 0.2 ml. each and two with 0.5 ml. each of the unglycerinated suspension respectively. Four more guinea-pigs are injected with 1 : 5 dilution of the glycerinated product in the same manner. No untoward reaction should be observed and none of the animals should die of anthrax during the period of observation for seven days.

(f) *Safety and Potency Test in sheep and goat*—Spore count of the glycerinated suspension is made after twentyone days from the date of glycerination. Three plates for each of the three dilution 10^{-5} , 10^{-6} , and 10^{-7} are made.

Eight sheep and eight goats each weighing not less than 18 kg. are injected subcutaneously in the following manner :—

two sheep : Each subcutaneously with 10 ml. of the stock suspension (for safety).

two goats : Each subcutaneously with 5 ml. of the stock suspension (for safety).

six sheep : Each subcutaneously with one million spores suspended in 50 per cent glycerine saline solution.

six goats : Each subcutaneously with one million spores suspended in 50 per cent glycerine saline solution.

None of these animals should die of anthrax. Twenty one days after vaccination, the animals are challenged with 100 lethal doses of virulent *B. anthracis* spores along with two healthy sheep and two goats as controls.

All the controls should die of anthrax within 72 hours after challenge and at least 66 per cent of the vaccinated animals should survive. The animals shall be observed for a minimum of ten days from the date of challenge.

(g) *Viable Count*—The vaccine when plated on suitable media should show 1.5 million *B. anthracis* organisms per ml. at the time of bottling, but not less than one million at any time before issue.

5. *Labelling and Storage*—Should comply with the requirements for “Labelling” and “Storage” as laid down in the general monograph on “Bacterial Vaccines”.

6. *Expiry Date*.—The date of expiry of the potency of the vaccine shall be not more than six months from the date of manufacture. The stock suspension can however be stored for two years.

Blackquarter Vaccine

1. *Synonym*—Blackleg vaccine or Quarter Evil Vaccine.

2. *Definition*—Blackquarter Vaccine is a culture of *Clostridium chauvoei* grown in a suitable anaerobic fluid medium and rendered sterile and toxic by the addition of Solution of Formaldehyde I. P. in such a manner that it retains its immunising properties.

3. *Preparation*—Cultures of *Cl. Chauvoei* are grown in a suitable anaerobic fluid medium and killed by the addition of a suitable concentration of Solution of Formaldehyde I. P. The final product shall be adjusted to pH. 7.0.

4. *Standards* :—

(a) *Description*—It is a yellowish brown liquid containing dead bacteria in suspension.

(b) *Identification*—It protects susceptible animals against infection with *Cl. chauvoei*.

(c) *Sterility Test*—Should comply with the test for sterility described in the general monograph on “Bacterial Vaccine”.

(d) *Safety and Potency Tests*—At least six adult healthy guinea-pigs each weighing 300 g to 450 g are injected subcutaneously each with 3 ml. of the product followed a week later by a second injection with the same dose. They should not show any systemic reaction but may show only a minimum of local reaction. Fourteen days after the second injection six of the vaccinated guinea-pigs are challenged intramuscularly with 25 viable spores of *Cl. Chauvoei* equivalent to 5 c.h.d. along with 0.2 ml. of a 5 per cent solution of calcium chloride. Two controls are used. The controls should die of the specific injection and at least 4 of the six vaccinated animals should survive before the product is passed for issue.

5. *Labelling and Storage*—Should comply with the requirements of “Labelling” and “Storage” as laid down in the general monograph on “Bacterial Vaccines.”

6. *Expiry Date*—The date of expiry of the potency of the vaccine shall not be more than twenty-four months from the date of manufacture.

Brucella Abortus (Strain 19 Vaccine) (Living)

1. *Synonym*.—Contagious Abortion Vaccine, (Strain 19) (Living).

2. *Definition*—*Brucella Abortus* (Strain 19) Vaccine (Living) is a suspension of a pure smooth living culture of *Br. abortus* of low virulence in normal saline solution.

3. *Preparation*—Forty eight to seventy-two hour old growth of *Br. abortus* (Strain 19) on potato agar medium in Roux flasks washed with buffered normal saline solution pH 6.4 and the pure growth from the flasks are pooled together. 0.5 ml. of the pooled product is mixed with 4.5 ml. of normal saline solution at pH 6.4 in graduated centrifuge tube and centrifuged at 3000 r.p.m. for one hour. The percentage of cell deposit is assessed by reading the amount of cell deposit obtained.

The concentrated suspension is then diluted with buffer normal saline solution so that the final product contains 0.72 per cent bacterial cell deposit.

4. *Standard* :

(a) *Description*—It is an almost white turbid liquid containing live bacteria in suspension.

(b) *Identification*—It consists of Gram-negative bacilli capable of protecting susceptible animals against Brucellosis.

(c) *Sterility Test*—Should comply with the test for sterility described in the general monograph on "Bacterial Vaccine."

(d) *Purity Test*—A smear of the finished products is examined microscopically after staining by Gram's method for evidence of any contamination. When grown on suitable media, *Br. abortus* should be obtained in a pure state.

(e) *Safety Test*—Two healthy guinea-pigs each weighing 300 g to 450 g. are inoculated subcutaneously each with 1.0 ml. of the final product. The guinea-pigs should not show excessive reaction of a toxic nature during the period of observation of ten days.

(f) *Potency Test*—Each of a group of four healthy guinea-pigs, drawn from a uniform stock and each weighing 300 g. to 450 g. is injected intramuscularly with 1 ml. of the vaccine, and is challenged nine weeks after vaccination by the intramuscular injection of 1 ml. of a suspension containing 5,000 fully virulent *Br. abortus* organisms. Each of a group of two unvaccinated guinea-pigs is similarly injected. After a further six weeks, the guinea-pigs are killed and cultures are made from their spleens. More than half of the vaccinated guinea-pigs contain no demonstrable *Br. abortus* in the spleen; all the controls are infected.

(g) *Viable Count*—The vaccine when plated on suitable media should show between 14,000 million and 18,000 million *Br. abortus* organisms per ml. At least 80 per cent of the brucella organisms should be in the smooth phase.

5. *Labelling and storage*—Should comply with the requirements of "Labelling" and "Storage" as laid down in the general monograph on "Bacterial Vaccines". The liquid vaccine shall be issued fresh as far as possible without allowing any period of storage after manufacture.

6. *Expiry Date*—The date of expiry of the vaccine shall be not more than five weeks from the date of manufacture.

Enterotoxaemia Vaccine.

1. *Synonyms*—Clostridium Welchii, Type D, Formal Culture : Pulpy Kidney Vaccine.

2. *Definition*—Enterotoxaemia Vaccine is a culture of a highly toxigenic strain of *Clostridium* type D, group is an anaerobic medium rendered sterile and toxic by the addition of Solution of Formaldehyde I.P. in such a manner that it retains its immunising properties.

3. *Preparation*—Selected toxigenic strain of *Cl. Welchii* type D, is grown in a liquid medium under conditions which ensure maximum epsilon toxin production. The culture is checked for purity and toxicity as tested in mice. Solution of Formaldehyde I. P. is added in suitable concentration and the formolised culture is kept at 37°C till the production is sterile and non-toxic.

4. *Standard*—

(a) *Description*—It is a yellowish brown liquid containing dead bacteria in suspension.

(b) *Identification*—When injected into susceptible animals it stimulates the production of epsilon antitoxin of *Cl. welchii*, type D.

(c) *Sterility Test*—Complies with the test for sterility described in the general monograph on 'Bacterial Vaccines'.

(d) *Safety and Potency Tests*—At least eight sheep each weighing not less than 18 kg. or twelve rabbits each weighing 1 kg. to 1.5 kg. are used for testing the safety and potency of each brew of the vaccine. Two sheep receive subcutaneously 10 ml. each and the other six sheep receive each 2.5 ml. of the product subcutaneously. The rabbits are given subcutaneously a dose of 5 ml. each. The sheep and rabbits are observed for five days. They should show only a minimum local reaction and no systemic reaction.

The sheep receiving 10 ml. are withdrawn from experiments after five days. Each of the other six sheep is inoculated with a second dose of 2.5 ml. fourteen days after the first injection. The rabbits are inoculated with 5 ml. as a second dose, after one month of the first inoculation. The day after the second inoculation the sera of sheep or rabbits are pooled separately. The pooled serum of each group of animal shall contain in each ml. not less than two international units of *Cl. welchii* epsilon antitoxin which is determined by testing on mice as follows :—

One ml of the pooled serum is mixed with one ml. of the epsilon toxin of *Cl. welchii* type D, containing 300 mouse-minimum-lethal-doses (mouse m.l.d.) and kept at room temperature for half an hour. At least two mice each weighing not less than 18 g. are each given intravenously 0.2 ml. of the mixture. As control two mice each weighing not less than 18 g. should each receive 0.2 ml. of the toxin containing 300 mouse m.l.d. per ml. diluted with equal volume of normal saline. The control mice should die within 1 to 2 hours while the mice receiving the mixture of serum and toxin should survive for at least two days. Sera containing one International Unit of epsilon antitoxin per ml. will be able to neutralise 150 mouse m.l.d. of epsilon toxin of *Cl. Welchii*, type D.

5. *Labelling and Storage*—Should comply with the requirements regarding "Labelling" and "Storage" as laid down in the general monograph on "Bacterial Vaccines".

6. *Expiry Date*—The expiry date of potency of the vaccine shall be not more than twelve months from the date of manufacture.

Fowl Cholera Vaccine (Polyvalent)

1. *Synonym*—*Pasteurella Septica Vaccine (Avian)*.
2. *Definition*—Fowl Cholera Vaccine is a formolised pure broth culture of virulent strains of *Pasteurella Septica (Avian)*.
3. *Preparation*—The strains are grown separately in nutrient broth for 48 hours at 37°C. The pure growth is killed by the addition of a Solution of Formaldehyde 1. P. in a suitable concentration. The cultures are then mixed in equal proportions and the final vaccine is bottled in suitable containers.
4. *Standard*—
 - (a) *Description*—It is a light yellow liquid containing dead bacteria in suspension.
 - (b) *Identification*—It protects susceptible birds against *P. aviseptica* infection.
 - (c) *Sterility test*—Complies with the test for “Sterility” described under the general monograph on “Bacterial Vaccines”.
 - (d) *Safety Test*—Two healthy young fowls each weighing not less than 400 g. or twelve healthy mice are inoculated subcutaneously each with 1 ml. of the final product. The birds should not show any untoward reaction during the period of observation for seven days.
5. *Labelling and Storage*—Should comply with the requirements of “Labelling” and “Storage” as laid down in the general monograph on “Bacterial Vaccines”.
6. *Expiry Date*—The date of expiry of potency of the Vaccine shall be not more than six months from the date of manufacture.

Hemorrhagic Septicaemia Adjuvant Vaccine

1. *Synonym*—*Pasteurella Septica Adjuvant Vaccine*.
2. *Definition*—The vaccine is a homogenous suspension of formolised agar-washed *Pasteurella septica* with liquid paraffin and lanolin.
3. *Preparation*—Pure growth of a highly antigenic strain of *P. Septica* in phase 1 grown on nutrient agar medium containing 0.5 per cent yeast extract is washed with 0.5 per cent formol saline. The pooled suspension is diluted with normal saline to contain approximately 2100 million *P. Septica* organisms per ml. The safety test of this adjusted suspension is conducted on four white mice each weighing not less than 18 g. and observed for three days before it is mixed with liquid paraffin and lanolin in suitable proportion.

The mixture is blended until a homogenous emulsion is obtained which is filled in suitable containers.

4. *Standard*—

- (a) *Description*—It is a white thick oily liquid containing dead bacteria in suspension.
- (b) *Identification*—It protects susceptible animals against infection with *P. Septica*.

(c) *Sterility Test*—It complies with the test for “Sterility” described in the general monograph on “Bacterial Vaccines”.

(d) *Safety Test*—Six white mice each weighing not less than 18 g. are inoculated intraperitoneally each with 0.5 ml. of the vaccine. None of the mice should die of pasteurellosis during the observation period for seven days.

(e) *Potency Test*—Three susceptible calves in good condition between the ages of nine months to three years are injected intramuscularly, each with 2 ml. of the vaccine, in the case of animals weighing upto 140 kg. and 3 ml. for heavier ones.

Three weeks later these animals along with two healthy animals of the same type and species are challenged subcutaneously with 18 hours old broth culture of *P. Septica* equivalent to at least 50 million mouse minimum infective dose. Both the controls should die of pasteurellosis and at least two out of the three protected animals should survive the challenge dose for a period of seven days.

5. *Labelling and storage*—Should comply with the requirements for “Labelling” and “Storage” as laid down in the general monograph on “Bacterial Vaccines”.

6. *Expiry Date*—The date of expiry of potency of the vaccine shall be not more than twelve months from the date of manufacture.

Haemorrhagic Septicaemia Vaccine (Broth)

1. *Synonym*—*Pasteurella Septica Vaccine (Broth)*.

2. *Definition*—Haemorrhagic Septicaemia Vaccine is formolised culture of a virulent strain of *Pasteurella septica* in nutrient broth.

3. *Preparation*—*P. Septica* culture is grown in nutrient broth at 37°C. The pure growth is killed by the addition of a solution of Formaldehyde I.P. in a suitable concentration.

4. *Standard*—

(a) *Description*—It is a pale yellow liquid containing dead bacteria in suspension.

(b) *Identification*—It protects susceptible animals against infection with *P. Septica*.

(c) *Sterility Test*—Complies with the test for “Sterility” described under the general monograph on “Bacterial Vaccines”.

(d) *Safety Test*—Four healthy rabbits each weighing 1 kg. to 1.5 kg. are inoculated subcutaneously each with 5 ml. of the product. There should be no untoward reaction during the period of observation for seven days. Alternately two rabbits and six mice may be employed. The dose for mice will be 0.5 ml.

5. *Labelling and Storage*—Should comply with the requirements of “Labelling” and “Storage” as laid down in the general monograph on “Bacterial Vaccines”.

6. *Expiry Date*—The date of expiry of potency of the vaccine shall be not more than six months from the date of manufacture.

*Salmonella Abortus Equi Vaccine*1. *Synonym*—Equine Abortion Vaccine.

2. *Definition*—Equine Abortion Vaccine is a mixture of equal parts of pure formalised cultures of smooth laboratory strains of *Salmonella abortus equi*.

3. *Preparation*—The strains are grown separately on plain agar in Roux flasks, for 24-28 hours at 37°C. The pure growth is washed with normal saline solution and the washings are pooled together. The suspension is standardised to contain approximately 600 million *Sal. abortus equi* organisms per ml. using normal saline solution as diluent. The culture is killed by the addition of sufficient quantity of solution of Formaldehyde I.P. in a suitable concentration and the product is kept at 37°C for seven days. Potassium alum is added to give a final concentration of 1 per cent.

4. *Standard*—

(a) *Description*—It is an opalescent liquid containing dead bacteria in suspension.

(b) *Identification*—It protects susceptible animals against infection with *Sal. abortus equi*.

(c) *Sterility Test*—Complies with the test for sterility described in the general monograph on "Bacterial Vaccines".

(d) *Safety Test*—Six white mice each weighing not less than 18 g. are inoculated intraperitoneally each with 0.5 ml. of the product. None of the mice should die of salmonellosis. The mice are observed for ninety-six hours.

5. *Labelling and Storage*—Should comply with the requirements for "Labelling" and "Storage" as laid down in the general monograph on "Bacterial Vaccines".

6. *Expiry Date*—The date of expiry of potency of the vaccine shall be not more than six months from the date of manufacture.

*Streptococcus Equi Vaccine*1. *Synonym*—Strangles Vaccine.

2. *Definition*—Streptococcus equi Vaccine is a phenolised culture of a number of different isolates of Streptococcus equi in glucose serum broth.

3. *Preparation*—Equal proportions of forty-eight hours old pure cultures of different isolates of Str. equi in serum glucose both are mixed together. The suspension is centrifuged and the deposit is washed with normal saline solution after removing the supernatant. The washed cells are suspended in normal saline and heated in a water bath 65°C for two hours. Phenol and normal saline are added to give a final concentration of 1200 million Str. equi organisms per ml. and 0.5 per cent of phenol in the vaccine.

4. *Standard*—

(a) *Description*—It is a slightly opalescent liquid containing dead bacteria in suspension.

(b) *Identification*—It protects susceptible animals against infection with Str. Equi.

(c) *Sterility Test*—Complies with the test for “Sterility” described in the general monograph on “Bacterial Vaccine”. The nutrient broth being replaced by glucose broth.

(d) *Safety Test*—Two ponies and two rabbits (each weighing not less than 1 kg.) are inoculated each with 10 ml. and 2 ml. respectively of the final product. The animals should not show any untoward reaction during the period of observation of seven days.

5. *Labelling and Storage*—Should comply with the requirements for “Labelling” and “Storage” as laid down in the general monograph on “Bacterial Vaccines”.

6. *Expiry Date*—The date of expiry of potency of the vaccine shall be not more than six months from the date of manufacture.

Old Adjuvant Vaccine against Pasteurellosis in Sheep and Goats

1. *Synonym*—Pasteurella Septica Adjuvant Vaccine for ovines and Caprines.

2. *Definition*—The vaccine is a homogenous suspension of formolised agarwashed Pasteurella septica of ovine origin with liquid paraffin and lanolin.

3. *Preparation*—Pure growth of highly antigenic strains (R1, R2, R4) in phase I grown separately on nutrient agar medium containing 0.5 per cent yeast extract is washed with 0.5 per cent Normal saline. Equal quantities of the suspension of three strains diluted with Normal saline to contain approximately 2100 million organisms per ml. is pooled together. The safety test of this adjusted pooled suspension is conducted in for white mice each weighing not less than 18 g. and observed for three days before it is mixed with liquid paraffin and lanolin in suitable proportion.

The mixture is blended until a homogenous emulsion is obtained which is filled in suitable containers.

4. *Standards*—

(a) *Description*—It is a white thick oily liquid containing dead bacteria in suspension.

(b) *Identification*—It protects susceptible animals against infection with *P. Septica*.

(c) *Sterility Test*—Complies with the test for “Sterility” described in the general monograph on “Bacterial Vaccines”.

(d) *Safety Test*—Six white mice each weighing not less than 18 g. are inoculated intra-peritoneally each with 0.5 ml. of the vaccine. None of the mice should die of Pasteurellosis during the observation period of seven days.

The vaccine is also inoculated into six sheep and six goats in a dose of 3 ml. each intramuscularly and are observed for a period of seven days. During this period none should die of Pasteurellosis.

(e) *Potency Test*—Not being done at present.

5. *Labelling and Storage*—Should comply with the requirements regarding “Labelling and Storage” as laid down in the general monograph on “Bacterial Vaccines”.

6. *Expiry Date*—The expiry date of Potency of the Vaccine shall be not more than twelve months from the date of manufacture.

(B) PROVISIONS APPLICABLE TO THE PRODUCTION OF VIRAL VACCINES

1. *Definition*.—(i) This part of the Schedule applies to viral vaccines live or inactivated made from any virus pathogenic to domestic animals and poultry and made from other modified viruses which have any antigenic value.

(ii) For the purpose of this part of the Schedule, a virus vaccine means, a sterile suspension or a freeze dried powder containing the modified living or inactivated virus particles, which in its original unaltered stage, causes disease from which the vaccine derives its name and which has been prepared from the blood or tissues of a suitable host in which it has been grown *in vivo* or from tissue culture.

2. *Staff of Establishment*—The establishment in which viral Vaccines, are prepared, must be under the direction and control of an expert in bacteriology with specialised training in virology and sufficient experience in the production of viral vaccines, and he shall be assisted by a staff adequate for carrying out the tests required during the preparation and standardisation of the vaccines.

3. *Proper Name*—The proper name of any viral vaccine shall be the name of the disease which is caused by the particular virus from which the vaccine is produced followed by the word "Vaccine" unless the Schedule otherwise provides, if there is no special provision in the Schedule such other name as is approved by the Licensing Authority. Provided that in the case of the undermentioned preparations the proper name of the vaccine shall be as follows :—

- (i) Fowl Pox Vaccines, Chick Embryo Virus (Living)
- (ii) Fowl Pox Vaccine, Pigeon Pox Virus (Living)
- (iii) Horse Sickness Vaccine (Living)
- (iv) Ranikhet Disease Vaccine (Living)
- (v) Ranikhet Disease Vaccine F Strain (Living)
- (vi) Rinderpest Goat Adapted Tissue Vaccine (Living)
- (vii) Rinderpest Lapinised Vaccine (Living)
- (viii) Rinderpest Lapinised Avianised Vaccine (Living)
- (ix) Sheep and Goat Pox Vaccine (Living)
- (x) Swine fever vaccine (crystal violet)
- (xi) Swine fever vaccine lapinised (Living).

4. *Records*—Viruses used in the preparation of vaccine must before being used for preparing a batch be thoroughly tested for purity, safety, sterility and antigenicity by the generally accepted tests applicable to the particular virus. The permanent records which the licensee is required to keep shall include a record of the origin, properties and characteristics of the seed virus from which the vaccines are made.

5. *Tests*—Viral vaccine shall be tested for sterility, safety and potency on suitable test animals and for viability in the case of live vaccines.

(a) *Sterility Test*—All vaccines shall be tested for sterility in accordance with rules 115 to 119. If the vaccine contains added bactericides or bacteriostatic, a quantity of medium sufficient to render the growth inhibitor ineffective is added to the sample or a suitable substance is added in a concentration sufficient to render the growth inhibitor ineffective but not itself to inhibit the growth of microorganisms.

(b) *Safety Test*—Suitable laboratory animals or large animals or birds may be employed to test the vaccine for safety. Details of safety test are given in the individual monograph.

(c) *Patency Test*—All virus vaccines for which potency test has been prescribed shall be tested for potency and only those which pass the potency test shall be issued. Details of the potency test are given in the individual monograph.

6. *Storage*—Live viral vaccines shall be stored, protected from light at sub-zero temperature as required. Other viral vaccines shall be stored at 2°C to 4°C but shall not be frozen.

7. *Condition of housing of animals*—(i) The animals used in the production of vaccine must be housed in hygienic conditions in premises satisfactory for this purpose.

(ii) Only healthy animals may be used in the production of vaccine. Each animal intended to be used as a source of vaccine must, before being passed for the production of vaccine be subjected to a period of observation in quarantine for at least seven days. During the period of quarantine the animal must remain free from any sign of disease and must be well kept.

8. *Labelling*—The provisions of "Labelling" as laid down for Bacterial Vaccines shall also apply to Viral Vaccines. The following additional information shall also be included on the label of the outside container.

(i) The name and percentage of bacteriostatic agent contained in the vaccine.

(ii) If the vaccine as issued for sale contains any substance other than the diluent, the nature and strength of such substance.

9. *Date of Manufacture*—For the purpose of this part of the Schedule, the date of manufacture shall be what is given unless otherwise stated in the individual monograph, as defined in sub-clause (b) of sub-rule (3) of rule 109.

Fowl Pox Vaccine Chick Embryo Virus (Living)

1. *Synonym*—Egg adapted Fowl Pox Vaccine (Living).

2. *Definition*—Fowl-pox vaccine, Chick-Embryo Virus (Living) is a suspension of a modified living virus (e.g. Mukteswar Strain) prepared from the chorioallantoic membrane (CAM) of the infected embryo and is either freeze dried or is issued as glycerinated liquid vaccine.

3. *Preparation*—Active chick-embryos obtained from *Salmonella pullorum* free flock, are used. Twelve to thirteen day old embryos are injected membrane (stock seed virus). The suspension of the stock virus is dropped on the CAM. After an incubation at 37°C for a suitable period membranes showing discrete or confluent lesions (pocks) are harvested.

These are homogenised with adequate quantity of antibiotics (penicillin and streptomycin) ampouled in 0.5 ml. quantities and freeze dried.

4. *Standard*—

(a) *Description*—Light mauve coloured scales.

(b) *Identification*—When reconstituted vaccine is applied to scarified area of the skin of a fowl it produces characteristic lesions of fowl pox. This product should afford protection against fowl pox.

(c) *Moisture Content*—Moisture Content in the finished product should not exceed 1.0 per cent.

(d) *Safety Test*—For testing each batch of fowl pox vaccine twelve healthy cockerels, or other suitable young chicken each weighing not less than 400 g. from the same source are taken. This group of twelve birds is immunized at least twenty one days previous to the test, with fowl pox vaccine. The vaccine under test is reconstituted in 5 ml. of 50 per cent glycerine saline and administered to fowls as follows :—

Three of the test birds are injected subcutaneously with 0.8 ml. or 10 times the field doses of the vaccine under test. This group serves to indicate whether the product is free from other viruses and bacteria causing septicaemia or not.

Three of the test birds are injected intratracheally with 0.3 ml. or 10 times the field dose of vaccine under test. This group serves to indicate whether the product is free from the virus of infectious laryngotracheitis and similar diseases.

Three of the test birds are injected intranasally with 0.2 ml. of the vaccine under test. This group serves to indicate whether the product is free from the virus of Coryza and similar disease.

The three remaining birds serve as controls. They are isolated and kept under observation for twenty-one days. The birds that succumb during the period of twenty-one days are subjected to a careful postmortem examination. The product is withheld from issue until the vaccine and the test birds are shown to be free from the causative agents of any extraneous disease.

(e) *Sterility test*—Complies with the tests for sterility as described under the general monograph on “viral vaccines”.

(f) *Potency Test*—For testing of potency three unsusceptible birds each weighing not less than 400 g. are vaccinated using the field dose by the stick method and examined for “takes”. Three weeks after vaccination these birds along with two unvaccinated controls are exposed to challenged virus and observed for fourteen days. The vaccinated birds should not manifest any reaction, while the controls should show active “takes”.

5. *Labelling*—Should comply with the requirement for “Labelling” as laid down in the general monograph on “Viral Vaccines”.

6. *Storage and Expiry date*—Freeze dried vaccine shall be expected to retain its potency for periods at temperatures as specified below :—

—15°C to —20°C—Twenty four months

2°C to 4°C—Twelve months.

Room temperature upto one month.

The liquid vaccine shall be expected to retain its potency for periods and temperatures as specified below :—

2°C to 4°C—six months

Room temperature—seven days

Fowl-Pox Vaccine Pigeon Pox Virus (Living)

1. *Synonym*—Fowl Pox Vaccine (pigeon pox scab).

2. *Definition*—Fowl vaccine, pigeon-pox virus (living) consists of pigeon pox virus in scabs collected from artificially infected pigeons and dried.

3. *Preparation*—Healthy pigeons are scarified on the legs and breast, with a suitable dilution of the suspension of pigeon-pox virus. The pigeons reacting satisfactorily and showing good takes are selected and the superficial skin layer scraped by means of sharp scalpel. The material so collected is freed from feathers, homogenised and dried or freeze dried. The dried pulp is powdered, sieved and ampouled in 0.3 g. quantities and sealed.

4. *Standard*—

(a) *Description*—Light cream coloured powder.

(b) *Identification*—When applied to feather follicles by vigorous rubbing, it produces mild reaction in fowls. The product should afford protection to fowls upto six weeks against fowl pox.

(c) *Safety Test*—For testing a batch of vaccine, twelve healthy cockerels, or other suitable young chicken from the same source are made available at the same time. This group of twelve birds is immunised at least twenty-one days previous to the test with fowl pox vaccine. The vaccine under test is reconstituted in 10 ml. of 50 per cent glycerine saline and administered to fowls as follows :—

Three of the test birds are injected subcutaneously with 0.3 ml. or 10 times the field dose of the vaccine to be tested. This group serves to indicate whether the product is free from organisms of septicaemia diseases.

Three of the test birds are injected intranasally with 0.2 ml. of the vaccine to be tested. This group serves to indicate whether the product is free from virus of Coryza and similar diseases.

The three remaining birds serve as controls. All the birds under test are isolated and held under observation for twenty-one days. All those that succumb are subjected to careful post-mortem examination. The product is withheld from issue until the vaccine and test birds are shown to be free from the causative agents of any extraneous diseases.

(d) *Sterility Test*—Complies with the tests for sterility described, under the general monograph on "Viral Vaccines".

(e) *Potency Test*—For testing the potency of a batch of vaccines three susceptible birds each weighing not less than 400 g. are vaccinated using the field dose by the follicular method and examined for 'takes'. Three weeks after vaccination these birds and two healthy susceptible controls are exposed to challenge virus and are observed for fourteen days. The vaccinated birds shall manifest no reaction, while the controls must have active "takes".

5. *Storage and Labelling*—Should comply with the requirements of 'Labelling' as laid down in the general monograph on 'Viral Vaccines'.

6. *Expiry date*—The vaccine shall be expected to retain its potency for periods at temperatures as specified below :—

—15°C to —20°C—two years

2°C to 4°C—twelve months

Room temperature—Upto one month.

Fowl Pox Vaccine—Pigeon Pox—Chick Embryos Virus (Living)

1. *Synonym*—Chick embryo adapted pigeon pox vaccine (Living).

2. *Definition*—Fowl pox vaccine (Pigeon Pox virus) chick embryo adapted virus (living) is a suspension of a modified living virus prepared from the chorioallantoic membranes of the infected embryos and is freeze dried.

3. *Preparation*—Active chick embryos obtained from *Salmonella Pullorum* free stock are used. Twelve to thirteen days old embryos are injected with a suitable dilution of the suspension of the infected membrane (stock seed virus) of chick embryo adapted pigeon pox virus. The suspension of the stock seed virus is dropped on the membrane. The inoculated eggs are incubated at 37°C for four days. One of the fourth day embryos that are living, are removed to a refrigerator for chilling for about one hour. Membranes showing discrete lesions (Pocks) are harvested. These are homogenised with adequate quantities of antibiotics, ampouled in 0.5 ml. quantities and freeze dried.

4. *Standards*—

(a) *Description*—Light mauve coloured scales.

(b) *Identification*—When reconstituted vaccine is applied to scarified area of the skin of a fowl, it produces characteristic lesions of Fowl Pox. This product should afford protection against pox.

(c) *Moisture content*—Moisture content in the finished product should not exceed 1.0 per cent.

(d) *Safety test*—For testing each batch chicks aged four to six weeks from the same source are taken. This groups of twelve birds is immunised at least twenty-one days previous to the last, with fowl-pox vaccine. The vaccine under test is reconstituted in 3 ml. of normal saline solution and administered as under :—

Three of the test chicks are injected subcutaneously with 0.3 ml. or 10 times the field dose of the vaccine under test. This group serves to indicate whether the product is free from other viruses and bacteria causing of septicaemia or not.

Three of the test chicks are injected intra-tracheally with 0.3 ml. or ten times the field dose. This group serves to indicate whether the product is free from the viruses of infections laryngotracheiti and similar diseases.

Three of the test chicks are injected with 0.2 ml. 1/N of the vaccine under test. This group serves to indicate whether the product is free from the virus of coryza and similar diseases.

For remaining three chicks serve as controls. They are isolated and kept under observation for twenty-one days. The birds that succumb during the period of observation are subjected to careful post-mortem examination. The product is withheld from issue until the vaccine and the test birds are shown to be free from the causative agents of any extraneous disease.

In addition to the above, similar groups of pigeons aged six to nine months old are also injected in a similar way to eliminate psittacosis.

(e) *Sterility Test*—Should comply with the tests for sterility described under the general monograph on 'Viral Vaccine'.

(f) *Potency test*—For testing potency of a batch of vaccine three susceptible chicks of three to four weeks of age are vaccinated by feather follicle method, (a few follicles on one leg are injected) and these are examined for 'takes'.

Three weeks after vaccination these chicks along with two unvaccinated chicks are exposed to challenge virus (virulent fowl pox virus) and observed for fourteen days. The vaccinated chicks should not manifest any reaction while controls should show active 'takes'.

5. *Labelling*—Should comply with the requirements for 'Labelling' as laid down in the general monograph on 'Viral Vaccines'.

6. *Storage*—The freeze dried product is expected to retain its potency for periods and temperature as specified below :—

—15°C to —20°C—two years

2°C to 4°C—twelve months.

Room temperature—upto one month.

Sheep Pox Vaccine (Living)

1. *Synonym*—Sheep Pox vaccine; Goat pox vaccine.

2. *Definition*—Sheep pox vaccine consists of sheep pox virus collected from sheep artificially infected with sheep pox virus and freeze dried.

3. *Preparation*—Healthy yearling sheep are infected artificially by subcutaneous infection on the undersurface of the previously shaved abdomen with 200—300 cc. of the freeze dried sheep pox virus (seed material) diluted in 1 : 1 Normal saline solution. On the sixth or seventh day after injection oedematous swelling develops in the injected area with thermal reaction. The sheep which develop good swelling are slaughtered and the gelatinous material present under the skin in the infected area is collected under sterile conditions. This material is mixed with 2 parts by volume of sterile peptone broth of pH 7.2 and homogenised. The homogenised suspension is filtered, ampouled in 0.5 ml. quantities and freeze dried.

4. *Standard*—

(a) *Description*—White scales.

(b) *Identification*—Reconstituted vaccine when applied over the scarified area of the skin of the abdominal region of sheep will produce characteristic local lesion of pox.

(c) *Moisture content*—The moisture content should not exceed 1.0 per cent.

(d) *Safety test*—Two rabbits each weighing not less than 1 kg. are injected subcutaneously each with 1 ml. of 1 : 100 dilution of the vaccine in normal saline solution. These animals are observed for fourteen days. The animals should remain normal.

(e) *Sterility Test*—Complies with the tests for sterility described under the general monograph on 'Viral Vaccines'.

(f) *Patency Test*—Four yearling sheep are vaccinated on the inner surface of the ear by scarification method. The contents of one ampoule of F.D. Sheep Pox vaccine are constituted in 10 cc. of 50% glycerine saline solution, characteristic takes develop in the scarified area with ulceration and scab formation. Three weeks later these and two more susceptible sheep (Controls) are challenged by scarifying with a suspension of the previous brow of the vaccine of the undersurface of the abdomen. The controls should develop typical lesions of pox and the vaccinated should remain normal.

5. *Labelling*—Should comply with the requirements of 'labelling' as laid down in the general monograph on 'Viral Vaccine'.

6. *Storage and expiry date*—The vaccine is expected to retain potency for period and temperature as specified below :—

—15°C to —20°C—two years.

2°C to 4°C—three months.

Room temperature—Fifteen days.

Horse Sickness Vaccine (Living)

1. *Synonym*—African Horse Sickness Vaccine; Mouse adapted Polyvalent Horse Sickness Vaccine (Living).

2. *Definition*—Horse sickness vaccine is a suspension of live mouse adapted strains of Horse Sickness Virus (onderstepoort) prepared from the brains of infected mice and is freeze dried.

3. *Preparation*—Thirty to thirty-five days old white mice are infected intracerebrally with 0.05 ml. of a suitable dilution of the seed virus (6 or 7 types, as the case may be). Groups of large numbers of mice are injected separately with each type of the virus and are housed at 27°C to 32°C. A majority of these become paralytic on the third and fourth day when they are sacrificed and their brains collected and stored at —15°C to —20°C till the day of processing. For preparing the polyvalent vaccine, equal number of brains collected from mice infected with different types of the virus are homogenised with 5-10 times its volume of sterile lactose buffer medium (pH 7.2) containing antibiotics. The suspension is centrifuged at 1500 r.p.m. for five minutes. The supernatant liquid is distributed in ampoules in suitable quantities and freeze dried.

4. *Standard*—

(a) *Description*—White scaly material.

(b) *Identification*—This product affords protection to horse against horse sickness.

(c) *Safety Test*—Four healthy mice thirty to thirty-five days old are injected intraperitoneally with 0.2 ml. of 10 : 1 dilution of the vaccine and kept under observation for ten days. All the mice should remain normal throughout the period of observation.

(d) *Sterility Test*—Should comply with the test for sterility described under the general monograph on 'Viral Vaccines'.

(e) *Viability Test*—Each batch of vaccine is titrated in tenfold dilutions using four mice of thirty to thirty-five days old for each dilution. Each mouse is injected intracerebrally with 0.05 ml. and kept under observation for ten days. Mortality and survival ratios are noted and Ld 50 is determined. The minimum acceptable titre is 10^{-4} Ld 50 per 0.05 ml.

5. *Labelling*—should comply with the requirements of 'Labelling' as laid down in the general monograph in 'Viral Vaccines'.

6. *Storage*—The vaccine may be expected to retain its potency for twelve months if stored -15°C to -20°C and about six months if stored in refrigerator at 2°C to 4°C .

Rabies Vaccine (Inactivated)

1. *Synonym*—Antirabic Vaccine (Inactivated).

2. *Definition*—Rabies vaccine is a suspension of the brain tissue of animals, that have been infected with a suitable strain of rabies fixed virus, inactivated with phenol or some other suitable agent.

3. The following particulars relating to this vaccine are the same as those relating to Antirabic vaccine described in Part D of Schedule F to these rules, namely :—

- (i) Strain of fixed Rabies Virus to be used;
- (ii) Staff of Establishment;
- (iii) Condition and housing of animals;
- (iv) Precaution to be observed in preparation;
- (v) Records;
- (vi) Issue.

4. *Preparation*—Healthy sheep or any other suitable species of animal are inoculated subdurally or intracerebrally with an appropriate dose of suspension of a suitable strain of rabbit brain passaged rabies fixed virus. The sheep or animals which get paralysed from the sixth day onwards after the inoculation are sacrificed and their brains collected aseptically. Brain tissue is weighed individually and a suspension of suitable concentration of brain tissue prepared in buffered saline is strained through gauze. The suspension treated with phenol or some other suitable inactivating agent is incubated for an appropriate period.

5. *Standard*—

(a) *Description*—A grey to pale yellow opalescent suspension.

(b) *Identification*—Appropriate doses protect mice against subsequent intracerebral inoculation with suitable strain of fixed rabies virus.

(c) *Safety test*—Not less than five mice, each weighing at least 18 gm., are inoculated intracerebrally with not less than 0.03 ml. of the suitably diluted vaccine. None of the animals should show symptoms of rabies or die of the disease during period of observation of three weeks.

(d) *Sterility Test*—Should comply with the test for sterility described under the general monograph on 'Viral Vaccine'.

6. *Labelling*—Should comply with the requirements of 'Labelling' as laid down in the general monograph on 'Viral Vaccines'. In addition the label on the container shall indicate the percentage of brain tissue present in the vaccine.

7. *Storage*—The vaccine may be expected to retain its potency for about six months if stored in refrigerator at 2°C to 4°C.

Rabies Vaccine (Living)

1. *Definition*—Rabies vaccine (living) is a freeze dried suspension of chick-embryo tissue infected with a suitable attenuated strain of rabies virus.

2. *Preparation*—It may be prepared by the following method. Seed virus consisting of a suspension of the Flury or other suitable strain of chick adapted virus that has been maintained by passage in chick embryos is injected into the yolk sacs of fertile eggs incubated for a suitable period. After incubation for a further ten days, the embryos are harvested and ground in water for injection to give 33 per cent suspension. The suspension is centrifuged to remove coarse particles and the supernatant fluid is distributed into ampoules in 3 millilitre quantities, and freeze-dried. The vaccine is reconstituted immediately before use by adding 3 millilitres of water for injection to the contents of an ampoule.

3. *Standard*—It complies with the requirements of general standard of viral vaccines for abnormal toxicity, sterility, and labelling with the following additions.

(a) *Description*—Dry honey-coloured flakes or powder, readily dispersible in water.

(b) *Identification*—It protects guinea pig against a subsequent inoculation of rabies street virus. It is distinguished from the inactivated Rabies vaccine by its ability to produce rabies encephalitic on intracerebral injection into mice.

(c) *Safety*—The guinea-pigs used in the test for potency should not show any marked local or systemic reaction during the three weeks following injection with the vaccine.

(d) *Sterility Test*—Complies with the tests for sterility described under the general monograph on 'Viral Vaccine'.

(e) *Potency Test*—The contents of an ampoule are dispersed in water for injection to give a 5 per cent suspension and not fewer than twenty guinea pigs, drawn from a uniform stock and each weighing 350 g. to 500 g., are each injected intramuscularly with 0.25 ml. of this suspension. Three weeks later, these guinea pigs and an equal number of similar unvaccinated control guinea pigs are each inoculated with 0.1 ml. of a suitable dilution of canine salivary gland suspension of street virus which is maintained as a 20 per cent suspension at 70°C or lower. The guinea pigs are observed for thirty days; not less than 80 per cent of the control guinea pigs die of rabies and not less than 70 per cent of the vaccinated guinea pigs are protected.

4. *Storage*—Freeze-dried vaccine should be stored at refrigeration temperatures of 2°C to 4°C.

5. *Labelling*—The life of the vaccine at room temperature and at refrigeration temperature should be stated on the label.

6. (a) *Action and uses*—Rabies vaccine (living) is used for the prophylactic inoculation of dogs against rabies; one injection should provoke a serviceable immunity lasting for at least a year. The vaccine has been used to a limited extent on cattle.

(b) *Dose*—By intramuscular injection : Dogs, the contents of one ampoule reconstituted in 3 ml. of water for injection; cattle five times the dog dose.

Ranikhet Disease Vaccine (Living)

1. *Synonym*—New castle Disease Vaccine (Living); pheumoenteritis Vaccine (Living).

2. *Definition*—Ranikhet Disease vaccine is a suspension of a modified living virus e.g. (Mukteswar strain) prepared from infected embryos and fluids and is freeze dried.

3. *Preparation*—Good fertile eggs obtained from *Salmonella pullorum* free flock are incubated in an egg incubator. Ten days old vigorous embryos are infected with 0.1 ml. of a suitable dilution of a suspension of the virus. Inoculation is done in the allantoic cavity. Embryos are incubated at a suitable temperature. Eggs showing dead embryos twenty-four hours after incubation are discarded. After forty eight hours incubation the eggs are candled and those showing dead embryos are chilled for a suitable period of time, while embryos alive beyond forty eight hours are discarded. The fluids and embryos are then collected and spot haemagglutination carried out. The material is homogenised in a blender and ampouled in aliquots of 0.5 ml. quantities and freeze dried.

4. *Standards*—

(a) *Description*—Light brown scales.

(b) *Identification*—This product affords protection to fowls against Ranikhet Disease.

(c) *Safety Test*—For testing each batch of freeze dried Ranikhet Disease Vaccine, twelve healthy young chickens, all from the same source each weighing not less than 400 g. are taken and immunised against Ranikhet Disease. Fourteen days later, these birds, are tested as follows with the contents of one ampoule suspended in 100 ml. of normal saline.

Three of the test birds are injected intratracheally with 0.1 ml. equivalent to ten times the field dose of the vaccine to be tested. This group serves to indicate whether the product is free from viruses or organisms of septicaemia disease.

Three of the test birds are injected intratracheally with 0.1 ml. equivalent to ten times the field dose of the vaccine to be tested. This group serves to indicate whether the product is free from the virus of infections laryngotracheitis, Coryza and similar diseases.

The three remaining birds serve as controls.

All the treated birds and controls are observed daily for fourteen days. All the test birds that succumb are subjected to careful postmortem

examination. The product is not issued until the birds under test are shown to be free from the causative agents of any extraneous diseases.

(e) *Sterility Test*—Should comply with the test for sterility described in the general monograph on 'Viral Vaccine'.

(f) *Potency Test*—Four susceptible birds eight to twelve weeks old and each weighing not less than 400 g. are vaccinated by injecting subcutaneously 1 ml. of a 10^{-5} dilution of the product. Two weeks after vaccination these birds and four non-protected birds are challenged by injecting subcutaneously each with 1.0 ml. of a 1 : 100 dilution of virulent virus (liver and spleen suspension) or 1.0 ml. of a 1 : 100 dilution of fluid from the embryo infected with virulent Ranikhet Disease virus. The non-protected birds should show symptoms of Ranikhet Disease and die and all the protected birds should remain normal during an observation period of fourteen days.

5. *Labelling*—Should comply with the requirements of 'Labelling' as laid down in the general monograph on 'Viral Vaccines'.

6. *Storage*—The vaccine when stored at -15°C to -20°C may be expected to retain the potency for about one year and about three months if stored in a refrigerator at 2°C to 4°C . The product should not be used if stored for more than ten days outside the refrigerator.

Ranikhet Disease Vaccine F Strain (Living)

1. *Synonyms*—New castle disease vaccine F Strain (Living).

2. *Definition*—Ranikhet disease vaccine F. strain is a suspension of a naturally modified living virus (F strain) prepared from the infected embryos, devoid of beaks and eyes and fluids in a frozen state.

3. *Preparation*—Good fertile eggs obtained from salmonella pullorum free flock are incubated in an egg incubator. Eight days old vigorous embryos are infected with 0.1 ml. of 1 : 100 suspension of Ranikhet Disease vaccine F strain virus. Inoculation is done via the allantoic cavity. Embryos are incubated at 37°C . Eggs are candled every day upto four days and the dead ones are discarded. Final candling of the embryos is carried out on the fourth day and only the living ones are chilled in a refrigerator for one hour. The fluids embryos are collected separately. The fluids are tested for spot haemagglutination and sterility test is carried out. The beaks and eyes balls of the embryos are removed. The materials are homogenised with adequate quantities of antibiotics in a cool warning blender and ampouled in aliquots of 0.5 ml. quantity and freeze dried.

4. *Standard*—

(a) *Description*—Light brown scales.

(b) *Identification*—This product affords protection to baby chicks against Ranikhet disease.

(c) *Moisture content*—The moisture content should not exceed 0.1 per cent.

(d) *Potency Test*—For testing each batch of the vaccine twelve one-day old chicks are given two drops 1/N of the field dose of the vaccine (5 ampoules selected at random may be reconstituted in 50 ml.) of cold normal saline solution. These are observed for fourteen days and the

vaccinated chicks should remain normal throughout the period of observation. This serves the safety test also.

On the fourteen days the vaccinated chicks are challenged two drops with 1 : 50 virulent Ranikhet Disease virus alongwith 8 control chicks. Four of the controls receive two drops 1/N of the virulent virus while the rest of the four receive 0.5 ml. of the virulent virus. The control chicks should succumb to the challenge virus showing symptoms of Ranikhet Disease while the protected chicks should remain normal throughout the observation period of fourteen days.

(e) *Sterility Test*—Should comply with the tests for sterility described in the general monograph on 'Viral Vaccines.'

5. *Labelling*—Should comply with the requirements of 'Labelling' as laid down in the general monograph on 'Viral Vaccine'.

6. *Storage*—The vaccine when stored at -15°C to -20°C may be expected to retain the potency for about one year and about three months if stored in a refrigerator at 2°C to 4°C . When removed from the refrigerator, the product should not be used later than ten days.

Rinderpest Goat adapted Tissue Vaccine (Living)

1. *Synonym*—Goat-adapted Cattle Plague Vaccine; Goat Tissue Vaccine (Living).

2. *Definition*—Rinderpest Goat-adapted Tissue Vaccine is the homogenised freeze dried preparation of spleen pulp of goats artificially infected with the suitable strain of rinderpest virus.

3. *Preparation*—Healthy susceptible goats are quarantined for a period of ten days. After this period a batch of selected goats are injected subcutaneously with 2 ml. of a suitable dilution of the suspension of the seed virus. The donor goats are sacrificed after a suitable period when the titre of the virus in the animal body is expected to be maximum, usually four days, and the spleen from animals free from any pathological change or signs are collected under sterile conditions. Smear from each spleen is examined microscopically to exclude spleen which are contaminated from the production batch.

The spleen is freed from fat and fascia and is blended into a smooth pulp in a grinder. The pulp is spread on a shallow dish of glass or stainless steel and is freeze dried.

The freeze dried pulp is then ground into a fine powder and sieved. The powder is ampouled in 0.25 g. or 0.125 g. quantities and freeze dried.

4. *Standard*—

(a) *Description*—Dark brown or chocolate coloured scales or powder.

(b) *Identification*—The product affords protection to susceptible animals against rinderpest.

(c) *Moisture content*—Not more than 1.0 per cent.

(d) *Safety Test*—Each batch of vaccine shall be tested for safety in laboratory animals and cattle or buffalo calves as follows :—

(i) *Small animals*—At least two guinea-pigs each weighing 300 g. to 450 g. and two adult rabbits each weighing 1 kg. to 1.5 kg. should be injected each with 1 ml. of 1 : 100 suspension of the vaccine subcutaneously and kept under observation for seven days. None of the animals should die. Alternatively, a batch of six white mice each weighing not less than 18 g. may be used, each mouse receiving 0.5 ml. of a dilution 1 : 100 suspension subcutaneously. None of the animals should die.

(ii) *Large animals*—Either cattle of good grade of susceptibility (hill cattle) or buffalo calves may be employed. For each batch of vaccine, three animals should be injected subcutaneously with 1 ml. of 1 : 8000 dilution of the vaccine. These animals should be kept under observation for twelve to fourteen days. None of the animals should show any untowards reactions.

(e) *Sterility Test*—Complies with the tests for sterility described under the general monograph on 'Viral Vaccines'.

(f) *Potency Test*—The animals receiving 1 ml. of 1 : 8000 dilution of vaccine used under safety test mentioned above and kept under observation for fourteen days, should be challenged with 1 ml. of 1 per cent. suspension of stock Rinderpest Virulent virus. None of the animals should die of rinderpest within a period of ten days. This test serves as a short potency test for each of the batches.

For conducting a detailed potency test the following procedure may be followed :—

Dilution 1 : 8000, 1 : 12,000 and 1 : 16,000 shall be tested and for each dilution three susceptible cattle or buffalo calves should be used. Each animal is inoculated subcutaneously with 1 ml. of a dilution of the vaccine, followed twelve to fourteen days later with a standard challenge dose of virulent rinderpest bull virus containing in 1 ml. of a 1 : 100 suspension of spleen tissue. Two unvaccinated bovines, each receiving the same quantity of the challenge dose act as controls. These are kept under observation for fourteen days. The end point of protection titre is assessed on the death or survival rate and the dose contained in one gramme of vaccine calculated on the basis of 20 to 40 minimum protective doses being equivalent to one vaccinating dose.

(g) *Virulence and viability Test*—Two to four goats each weighing not less than 18 kg. are injected with 2 ml. of 1 : 100 suspension of the vaccine and kept under observation for ten days. These animals should show reaction characterised by pyrexia (rise of about 2°C) anorexia and dullness.

5. *Labelling*—Should comply with the requirement of 'Labelling' as laid down in the general monograph on 'Viral Vaccines'.

6. *Storage*—The vaccine may be expected to retain its potency for twelve months if stored at -15°C to -20°C or about three months if stored at 2°C to 4°C.

Rinderpest Lapinised Vaccine (Living)

1. *Synonym*—Rabbit Adapted Cattle Plague Vaccine (Living) Lapinised Vaccine (Living).

2. *Definition*—Rinderpest Lapinised Vaccine is a suspension of a modified living virus (e.g. Nakamura III Strain) prepared with the blood spleen and mesenteric lymph glands of infected rabbits and is freeze dried.

3. *Preparation*—Adult rabbits possibly from a known stock, each weighing not less than 1 kg. free from coccidiosis and snuffles, are injected intravenously with 1 ml. of a suitable dilution of a suspension of the stock seed virus. Donor rabbits are sacrificed after a suitable period when the titre of the virus in the animals is expected to be the maximum usually the third day.

Ten millilitres of blood is collected from each rabbit in a defibrinating flask under aseptic condition. Later the animals are sacrificed and the spleen and mesenteric lymph glands collected. Each rabbit is subjected to a thorough post-mortem examination to observe lesions of rinderpest infection.

After harvesting, the blood and the organs (spleen and glands) are homogenised in a suitable proportion if necessary. Adequate quantities of penicillin and streptomycin may be added. The homogenised material is ampouled in suitable quantities and freeze dried.

4. *Standard*—

(a) *Description*—Dark chocolate coloured mass.

(b) *Identification*—This product affords protection to susceptible animals against rinderpest.

(c) *Moisture content*—Not more than 1.0 per cent.

(d) *Safety Test*—For testing a batch 2 guinea pigs each weighing not less than 300 g. are injected subcutaneously with 1 ml. of a 1 : 100 suspension of the vaccine. Alternatively, a group of six white mice each weighing not less than 18 g. is used. Each animal receives subcutaneously 0.5 ml. of 1 : 100 suspension of the vaccine. None of the test animals should die within a period of seven days.

(e) *Sterility Test*—Should comply with the tests for sterility described in the general monograph on 'Viral Vaccines'. If antibiotics have been added the inoculum should be neutralised before doing the test.

(f) *Potency Test*—Dilutions 1 : 100, 1 : 200, 1 : 400 and 1 : 800 shall be tested and for each dilution 2 susceptible cattle (hill bulls) or buffalo calves should be used. Each animal is inoculated subcutaneously with 1 ml. of a dilution of the vaccine, followed twenty-one days later with a standard challenge dose of a virulent rinderpest virus contained in 1 ml. of a 1 : 100 suspension of spleen tissue. Two unvaccinated bovines each receiving the same quantity of the challenge virus serve as controls. These animals are kept under observation for fourteen days. The end point of the protecting titre is assessed on the death or survival rate and the dose contained in one gramme of vaccine calculated on the basis of twenty minimum protective doses being equivalent to one vaccinating dose.

(g) *Virulence and Viability Test*—Four rabbits each weighing 1 to 1.5 kg. are injected subcutaneously with 1 ml. of 1 : 100 suspension of the vaccine. The animals should react typically showing all the symptoms of rinderpest in rabbits.

5. *Labelling*—Should comply with the requirements of 'Labelling' as laid down in the general monograph on 'Viral Vaccines'.

6. *Storage*—The vaccine may be expected to retain its potency for six months if stored at -15°C to -20°C or about a month if stored at 2°C to 4°C .

Rinderpest Lapinised Avianised Vaccine (Living)

1. *Synonym*—Lapinised Avianised Vaccine (Living).

2. *Definition*—Rinderpest Lapinised Avianised Vaccine is a suspension of a modified live rinderpest virus of low virulence prepared either with the whole chick embryo or the viscera of the infected chick embryo.

3. *Preparation*—Twelve or thirteen days old active chick embryos from a flock free from *Salmonella pullorum* infection are injected intravenously with a suitable dilution of the suspension of the stock seed virus in six per cent glucose solution. The embryos are incubated at 38.5°C for five days. At the end of this incubation period, eggs which show living embryos are selected for the preparation of the vaccine. The viscera of the chicks are harvested, care being taken to reject the gizzard and gall bladders. The material is homogenised in a blender with adequate quantities of antibiotics (penicillin and streptomycin added if necessary), and primary freeze dried done. This freeze dried material is ground into a fine powder, ampouled in suitable quantities and finally subjected to secondary freeze drying and sealed under vacuum.

4. *Standard*—

(a) *Description*—Pale cream or yellow coloured sterile powder.

(b) *Identification*—This product affords good grade of immunity to susceptible animals against rinderpest.

(c) *Moisture content*—Not more than 1.0 per cent.

(d) *Safety Test*—For testing each batch, a group of six mice each weighing not less than 18g. is used. Each mouse is injected subcutaneously with 0.5 ml. of a 1 : 100 suspension. Alternatively, two guinea pigs each weighing not less than 300 g. and two rabbits each weighing not less than 1 kg. are injected with 1 ml. of 1 : 100 suspension subcutaneously. These animals should not show any untoward reaction during the period of observation for seven days.

(e) *Sterility Test*—Should comply with the test for sterility as laid down in the general monograph on 'Viral Vaccines'.

(f) *Potency Test*—Healthy highly susceptible cattle (hill bulls) or buffalo calves should be used for testing the potency of each batch of vaccine in suitable dilution. For each dilution two highly susceptible animals should be used. Each animal is inoculated subcutaneously with 1 ml. of a dilution of the vaccine, followed twenty-one to twenty-eight days after with a standard challenge dose of a virulent rinderpest bull virus contained in 1 ml. of a 1 : 100 suspension of spleen tissue. Two unvaccinated bovines, each receiving the same quantity of the challenge virus serve as controls. All these animals are kept under observation for fourteen days. The end point of protective titre is assessed on the death or survival rate and the dose contained in one gramme of vaccine calculated on the basis of forty minimum protective doses being equivalent to one vaccinating dose.

5. *Labelling*—Should comply with the requirements of 'Labelling' as laid down in the general monograph on 'Viral Vaccines'.

6. *Storage and Expiry date*—The vaccine shall be expected to retain its potency for the period at temperatures as specified below :—

—15°C to —20° C	Six months.
2°C to 4°C	One month.

Sheep and Goat Pox Vaccine (Living)

1. *Synonym*—Sheep Pox vaccine. Goat Pox vaccine.

2. *Definition*—Sheep and Goat Pox Vaccine consists of the virus contained in the scabs collected from sheep artificially infected with the virus.

3. *Preparation*—Healthy yearling sheep are infected artificially on the shaved portion of the abdomen with a suitable dilution of the suspension of the stock seed virus 50 per cent glycerine saline solution. The material from the semi-dried areas where the pock lesions are evident is collected and dried over calcium chloride or phosphorus pentoxide under vacuum. Dry scabs are powdered, sieved, ampouled in suitable quantities and sealed.

4. *Standard*—

(a) *Description*—Light cream coloured powder.

(b) *Identification*—This product when applied to scarified area of the skin of the sheep or goats produces characteristic local lesions of pox and should afford protection to sheep and goat against Sheep and Goat Pox.

(c) *Safety Test*—Two rabbits each weighing not less than 1 kg. are injected subcutaneously each with 1 ml. of a 1 : 100 dilution of the vaccine in normal saline solution. These animals are observed for fourteen days. The animals should remain normal.

(d) *Sterility Test*—Complies with the tests for sterility described under the general monograph on 'Viral Vaccines'.

(e) *Potency Test*—Four yearling sheep are inoculated with 1 : 100 suspension of the vaccine in 50 per cent glycerine saline on a scarified area on the abdomen. Fourteen days later, these and two more susceptible sheep are inoculated by the same method with stock virus and observed for a period of fourteen days. The control animals should develop typical lesions of pox and the vaccinated animals should remain normal.

5. *Labelling*—Should comply with the requirement of 'Labelling' as laid down in the general monograph on 'Viral Vaccines'.

6. *Storage and Expiry date*—The vaccine shall be expected to retain its potency for period at temperatures as specified below :—

—15°C to —20°C	Twenty months.
2°C to 4°C	Three months.
Room Temperature	Fifteen days.

Fowl Spirochaetosis Vaccine (Chick Embryo Origin)

1. *Synonym*—Tick Fever Vaccine.

2. *Definition*—The vaccine consists of a merthiolated suspension of chorioallantoic membrane, internal viscera and blood of chick embryos infected with a vaccine strain of spirochaetes and freeze dried.

3. *Preparation*—Eleven days old developing chick embryos are infected with 0.2 ml. of sterile fresh blood containing spirochaetes via the chorioallantoic membrane. The inoculated embryos are incubated at 37°C and candled daily and the dead ones are discarded. On the seventh day the living embryos are chilled in the refrigerator for two hours. The chilled embryos are harvested separately and necrotic lesion in liver noted. Representative samples of blood should be examined for teeming spirochaetes. The internal viscera, chorio-allantoic membranes and the blood are collected. The material is pooled, weighed and held in deep freeze at -15° to -20°C for a period of one week. Thereafter the material is blended with equal quantity of Merthiolate (final concentration of merthiolate in the suspension should be 1 : 10,000) thoroughly for three times, each time the motor running at full speed and the vaccine is ampouled in 2 ml. quantities and freeze dried.

4. *Standard*—

(a) *Description*—Light brownish scales.

(b) *Identification*—The vaccine affords protection when inoculated into the fowls against spirochetosis.

(c) *Moisture content*—The moisture content should not exceed 1.0 per cent.

(d) *Safety and potency test*—Six healthy cockerals ten to twelve weeks old are used for this purpose. Each ampoule of vaccine is reconstituted in 10 ml. of cold distilled water and the six cockerals are injected intramuscularly each with 1 ml. of the reconstituted vaccine and the birds are observed for a period of ten days and the vaccinated birds should remain normal throughout the period of observation. The vaccinated birds are challenged with 0.2 ml. intramuscularly with virulent spirochaete blood along with two susceptible controls. Temperature and blood smear examination of the challenged birds and controls should be carried out daily for a period of ten days. The blood smears of vaccinated birds should remain negative for spirochaetes during the entire period of observation. The controls should react and show spirochaetes in the blood.

(e) *Sterility Test*—Complies with the tests for sterility described in the general monograph on 'Bacterial vaccine'.

5. *Labelling*—Should comply with the requirements of 'Labelling' as laid down in the general monograph on 'Bacterial Vaccine'.

6. *Storage*—The vaccine when stored at -15°C to -20°C may be expected to retain the potency for about one year and about two months if stored in refrigerator at 2°C to 4°C .

Swine Fever Vaccine Crystal Violet

1. *Synonym*—Crystal Violet Swine fever vaccine, Hog Cholera Vaccine.

2. *Definition*—Swine fever vaccine, crystal violet is a suspension of blood of swine that have been infected with a suitable virulent antigenic strain of swine fever virus, inactivated with 0.25 per cent crystal violet ethylene glycol at 37°C for fourteen days.

3. *Preparation*—Susceptible healthy pigs of six to seven months of age belonging to a well established strain or breed are used. Body weight of

these animals at this age may vary according to the breed but optimum weight is considered as between 75 to 100 kg. Animals used for production may be procured from well established farms and kept under quarantine for fourteen days. These are injected intramuscularly with a suitable dilution of the suspension of the virulent blood viruses. Bleeding of the clinically injected animals is carried out on the sixth day. The defibrinated blood from each animal is strained and stored separately in sterile glass containers. To the four parts of defibrinated blood, one part of 0.25 per cent crystal violet—ethylene glycol is added and the suspension after thorough mixing, is stored at 37°C (0.5) for two weeks. The product is filled in 20 ml. volumes in sterile vials and labelled on the completion of tests.

4. *Standard*—

(a) *Description*.—Very dark violet suspension.

(b) *Identification*.—This product affords protection against swine fever but not against African Swine Fever.

(c) *Safety Test*.—Two young pigs weighing about 15 to 30 kg. are injected subcutaneously each with 40 ml. of the vaccine batch to be tested. In addition, one unvaccinated susceptible pig is placed in contact.

(d) *Sterility Test*.—Should comply with the test for sterility described under general monograph on 'Viral Vaccines'.

(e) *Abnormal toxicity test*.—Two guinea pigs are given 1 ml. of vaccine intramuscularly.

Two guinea pigs are given 2 ml. of the vaccine intraperitoneally.

Two mice are given 0.5 ml. of the vaccine subcutaneously.

(f) *Potency Test*.—Four susceptible pigs weighing between 20-30 kg. are injected with 5 ml. of the vaccine subcutaneously. After twentyone days these are challenged with 1 ml. of suitable dilution of the challenge virus subcutaneously. The dose must contain at least 1000 minimum infective doses. At least two control pigs should be used.

5. *Labelling*.—Should comply with the requirement of 'Labelling' as laid down in the general monograph on 'Viral Vaccines'.

6. *Storage*.—The vaccine may be expected to retain its potency for twelve months if stored in refrigerator at 2°C to 4°C.

Swine Fever Vaccine Lapinised (Living)

1. *Synonym*.—Lapinised swine fever vaccine, freeze dried lapinised swine fever vaccine.

2. *Definition*.—Swine fever lapinised vaccine consists of the suspension of a modified live swine fever virus prepared from spleens of infected rabbits and is freeze dried.

3. *Preparation*.—Healthy adult rabbits weighing approximately 1000 gms. or over, free from coccidiosis snuffles etc. are injected intravenously with a suitable dose of a dilution of the modified rabbit adapted virus. Rabbits are sacrificed at the height of reaction and spleens are collected with sterile precautions. The collection is later homogenised in a blender using ten per cent yolk phosphate buffer as a diluent. The suspension is ampouled in 0.5 ml. quantities and freeze dried.

4. *Standard*—

- (a) *Description*—Light scales.
- (b) *Identification*—This product affords protection against swine fever.
- (c) *Moisture content*—The moisture content should not exceed 1.0 per cent.
- (d) *Safety Test*—Six mice are injected each with 0.5 ml. of a 1 : 100 suspension of the vaccine. These are kept under observation for seven days. None should die.
- (e) *Viability Test*—Two healthy rabbits are injected intramuscularly with 1 ml. of 1 : 100 suspension of the vaccine. These animals show thermal reaction.
- (f) *Sterility Test*—Should comply with the test for sterility described under the general monograph on 'Viral Vaccines'.
- (g) *Potency Test*—The vaccine batch under test should be tested on susceptible healthy pigs weighing between 20-30 kg. Two animals for each dilution may be used. The dilutions tested are 1 : 10, 1 : 25, 1 : 50 and 1 : 100. One millilitre of each of these dilutions is injected subcutaneously. One healthy, susceptible, unvaccinated in contact animal should be kept along with the vaccinated animals.

Fourteen to twenty-one days later these animals along with two controls are injected subcutaneously with 1 ml. of the challenge virus containing at least 1000 minimum infective doses.

5. *Labelling*.—Should comply with the requirements of 'Labelling' as laid down in the general monograph on 'Viral Vaccines'.

6. *Storage*.—The vaccine may be expected to retain its potency for six months if stored at temperature ranging between -10°C to -15°C and for seven days at 2°C to 4°C in the refrigerator.

PART II ANTISERA

Provisions applicable to the production of all Sera from Living Animals

1. *Definitions*.—(i) This Part of the Schedule applies to antibacterial sera, anti-viral sera and anti-toxic sera which are prepared by injecting bacteria or viruses or their products into buffalo-bulls or other suitable animals so as to produce active immunity which is manifested by the formation of anti-body.

(ii) For the purpose of this Part of the Schedule an anti-serum means sterile liquid anti-serum concentrated and unconcentrated, solutions of globulins or their derivatives or solid forms which can be reconstituted when necessary.

2. *Staff of Establishment*.—The establishment shall be under the direction and control of a competent expert in bacteriology and serology with adequate training in immunology and standardisation of biological products and knowledge of animal management. He shall be assisted by a staff adequate for carrying out the tests required during the course of preparation of the sera and standardisation of the finished products.

3. *Proper Name*.—The proper name of the antiserum shall be the recognised scientific name of the diseases or its causative organism or some

generally recognised abbreviations thereof preceded by the prefix 'anti', and followed by the word 'serum' as for example, 'Anti-anthrax serum'. The proper name of any antitoxin may be formed from the word 'Anti-toxin' preceded by the name of the organism from which the toxin was prepared, and followed, if desired, by a term indicating the source or the strain of that organism provided where there is no special provision in the Schedule, the name as approved by the Licensing Authority may be adopted.

4. *Records* :—

(1) The permanent records which the licensee is required to keep shall include the following particulars :—

(a) As to the culture—Evidence of the identity and specificity of the cultures.

(b) As to the procedure used in immunising the animals;

(i) The method of preparing the cultures or antigen used for immunisation.

(ii) The dosage and methods employed in administering the culture or antigen.

(iii) The period in the course of immunisation at which blood is withdrawn for the preparation of the serum.

(c) Any test which may have been applied to the serum to determine its content of specific antibodies or its specific therapeutic potency and purity.

(2) If the licensee desired to treat the performance of any tests recorded under sub-paragraph (i) (c) of this paragraph as determining the date of completion of manufacture for the purpose of rule 109 he shall submit full particulars of the proposed test to the Licensing Authority and obtain his approval.

5. *Cultures*.—The cultures used in immunising the animals shall be at all times open to inspection, and specimens shall be furnished for examination at the request of the Licensing Authority.

6. *Quantity*—

(a) Any antiserum shall be issued for veterinary use in the form of either.

(i) Actual serum, i.e., the liquid product of decantation of the coagulated blood or plasma without any addition, other than antiseptic or subtraction, or

(ii) A solution of the purified serum proteins containing the specific antibodies.

(b) At the time of issue, the liquid shall be clear or show at the most a slight opalescence or precipitate. Preparations of the natural serum shall not contain more than 10 per cent of solid matter. A solution of serum protein shall not contain more than 20 per cent of solid matter.

7. *Precautions to be observed in preparation*.—

(i) Laboratories where sera are exposed to the air in the course of the process of preparation must be separated by a sufficient distance from

stables and animal houses to avoid the risk of aerial contamination with bacteria from animal excreta, and must be rendered flyproof to prevent such contamination by insects. Such laboratories must have impervious walls and floors and must be capable of being readily disinfected when necessary.

(ii) A special room with impervious walls must be provided for the collection of blood from the living animals.

(iii) An efficient system of manure removal must be used which will prevent its accumulation in the vicinity of any room where blood or serum is collected or handled.

(iv) An adequate number of sterilizers must be provided for the sterilization of all glassware or other apparatus with which the serum may come into contact in the course of its preparation.

(v) All processes to which the serum is subjected during and after the collection from the animals, must be designed to preserve its sterility, but in the case of a artificially concentrated sera, it shall suffice that the process of concentration is conducted with scrupulous cleanliness and in such a manner as to avoid unnecessary dangerous contamination.

(vi) The laboratories in which the testing of sera for potency, sterility and freedom from abnormal toxicity are carried out must be adequate for the purpose. An adequate supply of animals for use in such tests and suitable housing for such animals must be provided.

(vii) Provision must be made for complying with any special conditions which may be laid down in the Schedule relating to the production and issue of the particular serum, in respect of which the licence is granted.

8. *Unhealthy or Infected Animals.*—If an animal used in the production of sera is found to be suffering from an infection except one produced by living organisms against which it is being immunized, or shows signs of serious or persistent ill health not reasonably attributable to the process of immunisation, the licensee shall immediately report the matter to the Licensing Authority and shall, if the authority orders an inspection and the Inspector so directs, cause such animals to be killed and a postmortem examination of it to be made, and take steps to prevent any serum obtained from the animal being sold or offered for sale until permission is given by the Licensing Authority. If the result of the postmortem is such as to bring under suspicion, the health of any of the other animals used for the production of sera, the Licensing Authority may prohibit the use of those animals for the production of sera or may take such other steps as may be necessary to prevent the issue of sera which may be dangerous to animal health.

Provided in the case of emergency, the person in charge of the establishment may order the destruction of an animal used in the production of sera and suspected of infection, and shall in that case given notice forthwith to the Licensing Authority and shall permit an Inspector to be present at the postmortem examination.

9. *Conditions and Housing of animals.*—

(i) The animals used in the production of sera should be adequately housed under hygienic environments.

(ii) Only healthy animals free from disease should be used in the preparation of sera.

(iii) Every animal intended to be used as the source of serum must be subjected to a period of observation in quarantine for at least seven days

before being admitted to the animal sheds in which the serum yielding animals are housed.

(iv) In case of horses and other equidae, every animal used as source of serum shall either be actively immunized against tetanus or shall be passively immunized against the disease by injection of tetanus antitoxin in such doses as to ensure the constant presence of that antitoxin in the blood during the whole period of the use of the animal as a source of serum.

Anti-Sera and their General Standard

Anti-sera contain the immune substances that have a specific prophylactic or therapeutic action when injected into animals exposed to or suffering from a disease due to a specific micro-organism or its toxin. Anti-sera are classified into three groups.

- (i) Antitoxic sera (Antitoxin).
- (ii) Antibacterial sera.
- (iii) Antiviral sera.

Antisera are usually issued in an unconcentrated form for animal use but may be concentrated and also freeze dried. However, for the purpose of the Schedule the word 'antisera' is also used for the unconcentrated liquid sera. A suitable bacteriostatic agent in a concentration sufficient to prevent the growth of micro-organisms is added to the liquid serum.

General Standard

1. *Description*.—Liquid native or unconcentrated antisera are yellow or yellowish brown in colour. They are initially transparent but may become turbid with age. They are almost odourless except for the odour of any bacteriostatic agent that may have been added.

2. *Identification*.—The test for identity is described in the individual monograph.

3. *Acidity or Alkalinity*.—All native antisera have a pH of 7.0 to 8.5.

4. *Abnormal Toxicity*.—All anti-sera shall comply with the following tests for freedom from abnormal toxicity.

(a) Two healthy mice each weighing not less than 18 g. are injected subcutaneously each with 0.5 ml. of the sample and observed for five days. None of the mice should show any abnormal reaction or die.

(b) Two healthy guinea-pigs each weighing 300 g. to 450 g. are injected subcutaneously each with 5 ml. of the sample and observed for seven days. None of the guinea-pigs should show any abnormal reaction or die.

5. *Sterility*.—All anti-sera shall comply with the tests for sterility described in rules 115 to 119.

6. *Potency*.—The potency of each preparation, when the available methods permit, is determined by the appropriate biological assay, and it is described under the individual monograph.

7. *Total Solids*.—Native antisera should not contain more than 10 per cent solid matter.

8. *Labelling*.—Should comply with the provisions for 'Labelling' as laid down for 'Bacterial Vaccines'.

9. *Storage*.—Liquid preparations of antisera shall be stored, protected from light at temperature between 2°C to 4°C and shall not be frozen.

10. *Date of Manufacture*.—The date of manufacture shall be unless otherwise specified in the individual monograph in this part is as defined in clause (b) of sub-rule (3) of rule 109.

11. *Containers*.—All antisera are distributed in sterilised containers of a material which is inert towards the substance and which are sealed to exclude micro-organisms.

12. *Expiry Date*.—The expiry date of potency of all sera shall not be more than twenty-four months after the date of manufacture.

Anti-Anthrax Serum

1. *Synonym*.—Bacillus Anthracis Anti-serum.

2. *Definition*.—Anti-anthrax serum is the serum of animals that confers a specific protection against *Baccillus anthracis*.

3. *Preparation*.—The antiserum may be prepared in buffalo bulls after repeated injections of cultures of *B. anthracis* of a virulent strain.

4. *Standard*.—It complies with the requirements in the general provisions for antisera under Description, Acidity or Alkalinity, Abnormal Toxicity, Sterility, Solids, Labelling, Storage and Expiry date.

(i) *Identification*.—It protects animals against infection with *B. Anthracis*.

Anti-Blackquarter Serum

1. *Synonym*.—Blackleg Antiserum, Clostridium Chauvoei-Anti-serum.

2. *Definition*.—Anti-Blackquarter serum is the serum of suitable animals containing the substances that have a specific neutralising effect on *Clostridium Chauvoei*.

3. *Preparation*.—It is prepared by injecting subcutaneously or intramuscularly increasing doses of formolised cultures of *Cl. Chauvoei* into buffalo bulls.

4. *Standards*.—It complies with the requirements described in the general provisions for antisera under Description, Acidity or Alkalinity, Abnormal toxicity, Sterility, Solids, Labelling, Storage and Expiry Date.

Identification.—It protects susceptible animals against infection with virulent strains of *Cl. Chauvoei*.

Anti-Fowl-Cholera Serum

1. *Synonym*.—Pasteurella Septica Antiserum (Avian).

2. *Definition*.—Fowl Cholera Antiserum is the serum of animals containing the substances that confer a specific protection to fowls against virulent strain of Pasteurella Septica (Avian).

3. *Preparation*.—Antiserum is prepared from buffalo bulls after they have been subjected to an injection of killed cultures of virulent strain of Pasteurella Septica (Avian) followed by injections of living cultures of the same organism.

4. *Standard*.—It complies with the requirements described in the general provision for anti-sera under Description, Acidity or Alkalinity, Abnormal toxicity, Sterility, Solids, Labelling, Storage and Expiry Date.

Identification.—It protects susceptible fowls against infection with *Pasteurella Septica* (Avian) and its homologous strains.

Anti-Haemorrhagic Septicaemia Serum

1. *Synonym*.—*Pasteurella Septica* Antiserum.

2. *Definition*.—Anti-Haemorrhagic Septicaemia Serum is the serum of animals containing the substances that confer a specific protection to susceptible animals against virulent strains of *Pasteurella Septica*.

3. *Preparation*.—The antiserum is prepared from buffalo-bulls after they have been subjected to repeated injections of formolised cultures of standard strain *Pasteurella Septica* with adjuvants, followed by suitable doses of virulent culture of the organism.

4. *Standard*.—It complies with the requirements described in the general provisions for antisera under Description, Acidity or Alkalinity, Abnormal toxicity, Sterility, Solids, Labelling, Storage and Expiry date.

Identification.—It protects susceptible animals against infection with homologous strains of *Pasteurella Septica*.

Anti-Rinderpest Serum

1. *Synonym*.—Cattle Plague Antiserum.

2. *Definition*.—Anti-rinderpest serum is the serum of buffalo bulls containing the substances that confer a specific immunity to susceptible animals against virulent strains of the virus of rinderpest.

3. *Preparation*.—The antiserum is prepared from buffalos who have reacted to a dose of virulent rinderpest virus, which is injected simultaneously with a predetermined quantity of antirinderpest serum so as to control the severity of the reaction (serum-simultaneous-method).

4. *Standard*.—It complies with the requirements described in the general provisions for antisera under Description, Acidity or Alkalinity, Abnormal toxicity, Solids, Labelling, Storage and Expiry Date.

(i) *Identification*.—It protects susceptible animals against rinderpest.

(ii) *Potency*.—Five Buffalo-calves of about one year of age in good condition are used for the test. Three are injected subcutaneously with the anti-rinderpest serum under test at the rate of 10 ml. per 46 kg. body weight, subject to a minimum of 20 ml. per animal. These together with the two remaining, are simultaneously injected subcutaneously at a different site with 1 ml. of a 1 : 100 dilution of spleen suspension of virulent bull-virus.

The animals should be observed for fourteen days during which time the serum treated animals should exhibit no symptoms of rinderpest other than rise in temperature and slight intestinal disturbances, while the controls develop more severe symptoms or die.

Salmonella Pullorum Anti Serum

1. *Synonym.*—*Salmonella Pullorum Anti-serum.*

2. *Definition.*—*Salmonella Pullorum anti-serum* is the sera from fowls and contains antibodies against *Salmonella Pullorum*. It is used for standardizing batches of *Salmonella Pullorum* antigens and also used as a control along with the sera suspected for pullorum disease.

3. *Preparation.*—The serum is prepared after intravenous inoculation with smooth culture suspension of *Salmonella Pullorum* in healthy birds.

4. *Standards.*—It complies with the requirements in the general provisions for anti-sera under Description, Acidity, Alkalinity, Sterility, Solids, Labelling, Storage and Expiry date.

Identification.—It should give positive agglutination with *Salmonella pullorum* antigen.

Standard Anti-Brucella Abortus Serum

1. *Synonym.*—National counterpart of standard anti-*Brucella abortus* serum.

2. *Definition.*—Standard anti-*Brucella abortus* serum is the serum which contains 1000 International Units (I.U.) per ml. and is used for standardizing batches of brucella antigens and is also used as a control along with the sera suspected for brucellosis.

3. *Preparation.*—The serum is prepared after intravenous inoculation of suspension of smooth culture of *B. abortus* (strain 99) in rabbits or cattle and subsequently diluting it suitably with brucella-free healthy serum so that when tested with standardized *Brucella abortus* tube test antigen, it gives 50% agglutination at 1/500 final serum dilution.

4. *Standard.*—It complies with the requirements in the general provision for anti-sera under Description, Acidity, Alkalinity, Sterility, Solids, Labelling, Storage and Expiry date.

Identification.—It should give agglutination with *Brucella* antigen.

PART III—DIAGNOSTIC ANTIGENS

Provisions Applicable to the Manufacture and Standardisation of Diagnostic Agents (Bacterial Origin)

1. *Definition.*—This Part of the Schedule applies to reagents of bacterial origin employed for various tests.

2. *Staff of Establishment.*—A competent expert in bacteriology with sufficient experience in the manufacture and standardisation of veterinary biological products shall be in charge of the establishment responsible for the production of various diagnostic agents of bacterial origin and he may be assisted by a staff adequate for carrying out the tests required during the preparation and standardisation of various diagnostic agents.

3. *Proper Name.*—The proper name of any diagnostic agent is the name of micro-organism from which it is made, followed by the word 'antigen' unless the Schedule otherwise provides, or, it may be derived from the name of the organism responsible for the causation of the disease or if there is no

special provision in the Schedule, the name approved by the Licensing Authority. In the case of the undermentioned preparations the proper name of the diagnostic agent may be as follows :—

1. Abortus Bang Ring (A.B.R.) Antigen.
2. Brucella Abortus Coloured Antigen.
3. Brucella Abortus Plain Antigen.
4. Johnin.
5. Mallein.
6. Salmonella Abortus Equi "H" Antigen.
7. Salmonella Pullorum Coloured Antigen.
8. Salmonella Pullorum Plain Antigen.
9. Tuberculin.

4. *Records*.—Culture used in the preparation of diagnostic agents of bacterial origin must, before being manipulated into an agent be thoroughly tested for identity by the generally accepted tests applicable to the particular micro-organism. The permanent record which the licensee is required to keep shall amongst other include a record of the origin, properties and characteristics of the cultures.

5. *Preparation*.—Diagnostic agents of bacterial origin are prepared from selected cultures after their careful examination for the identity, specificity, purity and antigenicity. They may be prepared in the following manner.

(a) *Formolised antigens*.—The selected pure culture strain grown in a suitable medium at an optimum temperature for an appropriate period. The pure growth is then exposed to the action of a solution of Formaldehyde I.P. in a suitable concentration and at an appropriate temperature for a suitable period.

(b) In some cases, the diagnostic agents are prepared by growing the organisms on suitable media and then deriving specific protein constituents of the bacteria by various methods.

6. *General Standard* :—

(a) *Description*.—Diagnostic agents may be clear opalescent or coloured liquids.

(b) *Identification*.—Some exhibit specific agglutination when mixed with the serum of the animals infected with homologous organisms and others when injected into the animal body in appropriate doses cause specific reactions like hypersensitiveness, local and general reaction, if the animal is infected with homologous organisms.

(c) *Sterility Test*.—All antigens shall be tested for sterility in accordance with rules 114 to 119.

(d) *Standardisation*.—It is carried out either by determining the definite cell concentration in the product or by observing the general and local reactions in healthy and artificially infected animals with various standard dilutions of the product.

7. *Labelling*.—As under general provisions for the bacterial vaccines with the addition that it is meant for diagnostic purposes only.

8. *Storage*.—All antigens are stored, protected from light at a temperature between 2°C to 4°C.

9. *Date of Manufacture*.—The date of manufacture shall be unless otherwise specified in the individual monograph in this part as defined in clause (b) of sub-rule (3) of rule 109.

Abortus Bang Ring (A.B.R.) Antigen

1. *Synonym*.—Milk Ring Test Antigen.

2. *Definition*.—The antigen is a suspension of pure growth culture of standard strain of *Brucella abortus* strain 99 strained supravivally with 2, 3, 5, triphenyl tetrazolium chloride suspended in 0.85 per cent saline containing 1 per cent glycerol and 1 per cent phenol.

3. *Preparation*.—Smooth strain of *Brucella abortus* strain 99 is grown on potato infusion agar for 48 to 72 hours in Roux flasks, at 37°C. Condensation fluid if any is pipetted off before washing. Each flask is washed with about 20 ml. of normal saline. The pooled washing is filtered through a gauze and the filtrate is collected in a measuring cylinder. To every 500 ml. of the filtrate 1 g. of 2, 3, 5, triphenyl tetrazolium chloride is added immediately. The container is shaken for thirty minutes till the tetrazolium salt is dissolved. The product is taken out and kept at 37°C for two hours. After incubation the product is heated at 65°C in a water bath for thirty minutes. It is cooled and centrifuged at 3000 r.p.m. for one hour. The supernatant is pipetted off and sediment is suspended in normal saline containing 1 per cent glycerol and 1 per cent phenol and filtered through sterile cotton wool. This forms concentrated antigen.

Standardization of the Strained Antigen

An aliquot portion of the microbial suspension stained with phenyltetrazolium is taken, representing the initial undiluted suspension. 1 ml. per tube of this initial undiluted stained suspension is added to six test-tubes, followed by increasing quantities of the glycerolphenol diluent as follows :—

Tube	Undiluted Stained Suspension	Diluent
1	1	0.6
2	1	0.8
3	1	1.0
4	1	1.2
5	1	1.4
6	1	1.6

The contents of each tube are then diluted tenfold with the same diluent and serve as antigen for a tube agglutination test with the Standard Serum (or its national counterpart). In this way, six sero-reactions will be carried out. During this procedure, the concentrated strained microbial suspension should be kept in the refrigerator at 4°C.

The agglutination reactions are read after forty-eight hours' at the agglutination titre of the Standard Serum, previously determined with the

usual unstained antigen in the tube test, corresponding to the correct dilution of the standard antigen.

The next step, therefore, is to dilute the concentrated stained suspension to the same extent as the tube whose tenfold dilution has given the correct agglutination titre, i.e. the concentration of antigen in the tube before the tenfold dilution had been made.

4. *Standards* :—

(a) *Description*.—It is a red colour liquid containing dead bacteria in suspension.

(b) *Identification*.—It shows formation of a specific cherry red coloured ring in the cream layer when mixed with pooled samples of milk taken from animals suffering from brucellosis.

(c) *Sterility Test*.—Should comply with the tests for sterility described in the general monograph on 'Diagnostic Antigen'. The tests shall, however, be done before colouring.

5. *Labelling and Storage*.—Should comply with the requirements of 'Labelling' and 'Storage' as laid down in the general monograph on 'Diagnostic Antigen'.

6. *Expiry Date*.—The date of expiry of potency shall be not more than nine months from the date of manufacture when stored at 2°C to 4°C.

Brucella Abortus Coloured Antigen

1. *Synonym*.—*Brucella abortus* Cotton Strain 99 coloured Antigen.

2. *Definition*.—*Brucella Abortus* coloured Antigen, is a suspension of pure smooth cultures of *Brucella abortus* strain 99 in phenolised glycerine saline, the bacteria being coloured by the addition of crystal violet and brilliant green. This antigen is used for plate test for serological diagnosis of brucella infection.

3. *Preparation*.—Seventy-two hours old growth of *Brucella Abortus* strain ninety-nine in smooth form on potato infusion agar medium in Roux flasks is washed with phenolised glycerine saline (containing 12 per cent sodium chloride, 20 per cent glycerine and 0.5 per cent phenol). The washed growth is filtered through a pad of absorbent cotton wool and the suspension is coloured by the addition of 1 ml. each of 1 per cent aqueous solution of crystal violet and brilliant green for every 250 ml. of the suspension. The product is heated for sixty minutes in a water bath at 60°C before it is standardised.

4. *Standard* :—

(a) *Description*.—It is a greenish violet liquid containing dead bacteria in suspension.

(b) *Identification*.—It gives specific agglutination when mixed with the serum of the animal infected with brucella organism.

(c) *Sterility Test*.—Should comply with the tests for sterility described in the general monograph on 'Diagnostic Antigen'.

(d) *Standardisation*.—0.5 ml. of the antigen is mixed with 4.5 ml. of normal saline solution in Hopkins graduated tube. The mixture is centrifuged at 3000 r.p.m. for sixty minutes and the percentage of bacterial cells

present in the original antigen is assessed by noting the height of the cell deposit. The antigen is then standardised so as to contain 10 per cent cell deposit.

5. *Labelling and Storage*.—Should comply with the requirements of 'Labelling' and 'Storage' as laid down in the general monograph on 'Diagnostic Antigens'.

6. *Expiry Date*.—The date of expiry of potency shall be not more than nine months from the date of manufacture when stored at 2°C to 4°C.

Brucella Abortus Plain Antigen

1. *Synonym*.—Brucella Abortus Strain 99 Plain Antigen.

2. *Definition*.—Brucella Abortus Plain Antigen is a suspension of a pure smooth culture of Brucella abortus strain 99 in phenol-saline.

3. *Preparation*.—Seventy-two hours old growth of Br. Abortus strain 99 in smooth form on potato infusion agar medium in Roux flasks is washed with normal saline solution. The washed growth is filtered through a pad of absorbent cotton wool and the suspension is kept at 60°C for sixty minutes on a water bath to kill the organisms. It is then preserved by the addition of phenol in a final concentration 0.5 per cent.

4. *Standard* :—

(a) *Description*.—An opalescent liquid containing dead bacteria in suspension.

(b) *Identification*.—It gives specific agglutination when mixed with the serum of animals infected with brucella organism.

(c) *Sterility Test*.—Should comply with the tests for sterility described in the general monograph on 'Diagnostic Antigen'.

(d) *Standardisation*.—Mix the concentrated antigen well and dilute 1 ml. with 0.5 per cent phenol saline until it corresponds to about Tube 4 of Brown's opacity tubes. Further dilutions of the antigen adjusted to opacity tube No. 4 are made. The particular dilution that gives 50 per cent agglutination with anti-brucella abortus serum (containing 1000 International Units) at 1 : 500 final serum dilution, is assessed as the diluting factor for the concentrated antigen. The bulk of the concentrated antigens is accordingly diluted for issue as standard antigen.

5. *Labelling and Storage*.—Should comply with the requirements of 'Labelling and Storage' as laid down in the general monograph on 'Diagnostic Antigen'.

6. *Expiry Date*.—The date of expiry of potency shall be not more than nine months from the date of manufacture when stored at 2°C to 4°C.

Johnin

1. *Definition*.—Johnin is a preparation of a fluid medium in which *Mycobacterium paratuberculosis* has been grown in artificial culture and which has been freed by filtration from the bacilli.

2. *Preparation*.—Young culture of selected strain of Myco. *paratuberculosis* of bovine origin is grown on synthetic medium and incubated at 37°C for ten to twelve weeks. Flasks showing luxuriant and pure growth are steamed for three hours thereafter kept at room temperature overnight. The

contents are filtered through fine meshed sieve. The filtrate is concentrated over a steam bath to one-tenth of its original volume and kept in cold storage for fourteen days before being filtered through Seitz filter. The product is dispensed in ampoules and hermetically sealed.

3. Standards :—

(a) *Description*.—A yellowish brown to brownish liquid.

(b) *Identification*.—It produces hot, painful and oedemateous swelling at the site of inoculation in animals infected with *Myco-paratuberculosis* organism.

(c) *Sterility Test*.—Should comply with the test for sterility described in the general monograph on 'Diagnostic Antigens'.

(d) *Potency Test*.—Two animals, previously infected with *Myco-paratuberculosis* and two healthy animals are each injected intrademally in the neck region with 0.1 ml. of the product. Forty-eight hours later, the injection is repeated at the same site. The product should produce a typical reaction in the infected animals in the form of a hot painful and oedemateous swelling at the site of inoculation persisting for at least forty-eight hours after the second injection. Control animals should not show such reaction.

4. *Labelling and Storage*.—Should comply with the requirement of 'Labelling' and 'Storage' as laid down in general monograph on 'Diagnostic Antigens'.

5. *Expiry Date*.—The date of expiry of potency shall be not more than two years from the date of manufacture when stored at 2°C to 4°C.

Malleins

1. *Definition*.—(i) Malleins are preparations of fluid media in which the *Actinobacillus mellei* has been grown in artificial culture and which have been freed by filtration from the bacilli.

(ii) For the purposes of this Schedule malleins are classified into (a) Mallein-subcutaneous and (b) Mallein intradermopalpebral (I.D.P.).

2. Preparation :—

(a) *Mallein Subcutaneous*.—Three to four weeks old pure growth of standard strain of *A. mallei* grown on synthetic medium is steamed for one hour in Koch's steam sterilizer. One part of 5 per cent phenol solution is added to every nine part of the dead culture which is then filtered through Seitz filter.

(b) *Mallein Concentrated*.—The procedure is the same as for Mallein Subcutaneous except, that the filtrate is evaporated in porcelain dish over steam to half the original volume before addition of phenol. Five per cent phenol solution is added in sufficient quantity to the concentrated product, to give a final concentration of 0.5 per cent.

3. Standards :—

(a) *Description*.—A yellowish to brown viscous liquid

(b) *Identification*.—It produces hot tense, painful swelling when injected into the animals infected with *A. mallei* organisms.

(c) *Sterility Test*.—Should comply with the tests for sterility described in the general monograph on 'Diagnostic Antigens'.

(d) *Potency Test* :—

(i) *Mallein subcutaneous*.—Two ponies, previously sensitised with *A. Mallei* and controls, are injected each with 1 ml. of the product subcutaneously in the neck region. The animals are observed for local reaction and rise in temperature. Local reaction is manifested by a hot tense, painful swelling becoming prominent within twenty-four hours. The rise in temperature is observed by recording the body temperature at the time of inoculation and subsequently at short intervals. A rise in temperature of 1°C or more above normal is indicative of infection.

(ii) *Mallein Intra-dermo-Palpebral (I.D.P.)*.—Two ponies previously sensitized with *A. mallei* and two healthy ponies are injected intradermally with 0.2 ml. of the product near the rim of the lower eye lid of one eye. Typical reactions such as painful swelling of the palpebral tissue with mucopurulent discharge from the eye is indicative of infection. The two healthy ponies should not show such reactions.

Similar test in other eye is performed with a previously determined patient mallein using as a standard. When the local reactions produced by intradermo palpebral infections of the two preparations are comparable the batch is passed for issue.

4. *Labelling and Storage*.—Should comply with the requirement of 'Labelling' and 'Storage' as laid down in the general monograph on 'Diagnostic Antigen'.

5. *Expiry Date*.—The date of expiry of potency shall be not more than two years from the date of manufacture when stored at 2°C to 4°C.

Salmonella Abortus Equi 'H' Antigen

1. *Synonym*.—Equine Abortion Diagnostic Antigen.

2. *Definition*.—*Salmonella Abortus Equi Antigen* is suspension of a pure smooth culture of actively motile *Salmonella Abortus equi* in formal saline.

3. *Preparation*.—Standard stain of *S. abortus equi* is grown on nutrient agar in Roux flasks at 37°C for twenty-four hours. The pure growth in Roux flasks is washed with normal saline and diluted to contain approximately 800 million organisms per ml. Solution of Formaldehyde I.P. is added to give a final concentration 0.5 per cent and the formolised product is incubated at 37°C for twenty-four hours. The final product is dispensed in suitable containers.

4. *Standards* :—

(a) *Description*.—A slightly opalescent liquid containing dead bacteria in suspension.

(b) *Identification*.—It gives specific agglutination when mixed with the serum of the animals infected with *S. abortus equi* organisms.

(c) *Sterility Test*.—Should comply with the test for sterility described in the general monograph on 'Diagnostic Antigens'.

5. *Labelling and Storage*.—Should comply with the requirements of 'Labelling and Storage' as laid down in the general monograph on 'Diagnostic Antigens'.

6. *Expiry Date*.—The date of expiry of potency shall be not more than nine months from the date of manufacture when stored at 2°C to 4°C.

Salmonella Pullorum Coloured Antigen

1. *Synonym*.—Bacillary White Diarrhoea (B.W.D.) Antigen.

2. *Definition*.—The antigen is a suspension in a solution containing 1 per cent formaline, 1 per cent KH_2PO_4 and 0.85 per cent Sodium Chloride of pure smooth culture of standard strain of *Salmonella Pullorum*.

3. *Preparation*.—Standard strain of *S. Pullorum* is grown on sulphur agar medium in Roux flasks for five days at 37°C. The pure growth is washed with 1.0 per cent Formol Saline.

Standardisation

The antigenic cell suspension is then centrifuged (preferably in cold centrifuge) for half an hour at 4000 rotations per minute and the packed cell volume determined. The packed cell is then re-suspended in a solution containing 1 per cent formalin, 1 per cent KH_2PO_4 and 0.85 per cent sodium chloride, 1 ml. of packed cell is suspended in 10 ml. of the resuspensionary solution, mixed thoroughly and is passed through a cotton wool pad. The turbidity of the antigenic suspension is usually between 100 to 125 times Mac Farland scale standard and optimum 3 cc. of a 1 per cent aqueous solution of crystal violet are added to 100 ml. of the antigenic suspension. After making the dye the antigen is allowed to stand forty-eight hours before use. The average yield per Roux flasks of culture medium is about 50 ml. The antigen should be bottled in 10 ml. or 20 ml. quantity in amber-coloured bottles and corked with rubber caps and paraffin sealed and preserved until required for use within the expiry period. This antigen reacts instantly with the blood of all carrier birds and remains permanently negative with that of non-infected birds.

This antigen gives good reactions with positive sera whose titre is even as low as 1 : 20.

4. *Standard* :—

(a) *Description*.—Violet coloured liquid containing dead bacteria in suspension.

(b) *Identification*.—It gives specific agglutination when mixed with the serum of birds infected with *S. Pullorum* infection. It is used for carrying out plate agglutination tests for serological diagnosis for *S. Pullorum* infection in birds.

(c) *Sterility Test*.—Should comply with the test for sterility described in the general monograph on 'Diagnostic Antigens'. The tests shall be done before addition of 'Crystal Violet'.

7. *Labelling and Storage*.—Should comply with the requirements 'Labelling' and 'Storage' as laid down in the general monograph on 'Diagnostic Antigens'.

8. *Expiry Date*.—A six month expiration date for this antigen is recommended. However, it is advisable to use fresh ones as far as possible. This

antigen should be preserved at 4°C to 6°C in dark place in the refrigerator and should not be exposed to hot weather condition for longer than necessary before use in the field.

Salmonella Pullorum Plain Antigen

1. *Synonym*.—Bacillary White Diarrhoea (B.W.D.) Plain Antigen.

2. *Definition*.—The antigen is a suspension of pure smooth culture of *Salmonella pullorum* in phenol saline.

3. *Preparation*.—Forty-eight hours old pure culture of smooth strain of *S. pullorum* is washed with 0.5 per cent phenol saline and the pooled suspension is adjusted to contain approximately 800 million organisms per ml. by the addition of more carbol saline. The suspension is kept at room temperature for twenty-four hours, and dispensed in suitable containers.

4. *Standard* :—

(a) *Description*.—An opalescent liquid containing dead bacteria in suspension.

(b) *Identification*.—It gives specific agglutination when mixed with the serum of birds infected with *S. Pullorum*.

(c) *Sterility Test*.—Should comply with the tests for sterility described in the general monograph on 'Diagnostic Antigen'.

5. *Labelling and Storage*.—Should comply with the requirements of 'Labelling' and 'Storage' as laid down in the general monograph on 'Diagnostic Antigens'.

6. *Expiry Date*.—The date of expiry of potency shall be not more than nine months from the date of manufacture when stored at 2°C to 4°C.

Tuberculin

(i) Tuberculines are preparations of fluid media on which *Mycobacterium tuberculosis* has been grown in artificial culture and which has been freed by filtration from the bacilli.

(ii) For the purposes of the Schedule tuberculines are classified in (a) Tuberculine-Subcutaneous (b) Heat Concentrated Synthetic Medium (H.C.S.M.) Tuberculine (c) Avian tuberculine.

2. *Preparation* :—

(a) *Tuberculine subcutaneous*.—Flasks containing Henley and Dorset synthetic medium are inoculated with standard human strains of *Myco. tuberculosis* previously grown on glycerol-beef broth medium for ten days. After ten to twelve weeks of incubation at 37°C, flasks containing pure growth are steamed for three hours. The contents are filtered through fine meshed sieve and the volume is made up to its original with phenolised distilled water such that the final concentration of phenol is 0.5 per cent. It is then filtered through Seitz filter.

(b) *Heat Concentrated Synthetic Medium (H.C.S.M.) Tuberculine*.—To the strained liquid obtained after sieving as in the method of preparation of Tuberculine subcutaneous, glycerol is added in the proportion of 122 ml. per litre of the original volume of medium used. The mixture is evaporated to one-fifth of the original volume on a steam bath. An equal volume of

1 per cent phenol in distilled water is added after the mixture is cooled. The product is stored at 47°C for fourteen days before it is filtered through Seitz filter. It is then dispensed in ampoules.

(c) *Avian Tuberculine Concentrated*.—The procedure is the same as for Tuberculine Concentrated (H.C.S.M.) except that standard strain of Myco-tuberculosis (Avian) is used in its preparation.

3. Standard :—

(a) *Description*.—A yellowish brown viscous liquid.

(b) *Identification*.—When injected intradermally into the animal infected with tuberculosis diffused swelling occurs depending upon the allergic status of the animal, the magnitude of dose and specificity of the product. In non-infected animals this reaction is not observed.

(c) *Sterility Test*.—Should comply with the test for sterility described in the general monograph on 'Diagnostic Antigens'.

(d) *Potency Test*.—(i) *Tuberculine subcutaneous*—six large white guinea-pigs each weighing not less than 300-450 g. are individually inoculated intramuscularly with 0.5 mg. (Moist growth from solid plants) of Mycobacterium tuberculosis three weeks prior to test of each batch of tuberculine; the following dilutions of (a) test tuberculine and (b) standard tuberculine are used :—

1 in 200, 1 in 400, 1 in 800 and 1 in 1600.

The six sensitized guinea-pigs are depilated on one flank and after about twenty-four hours each animal inoculated intradermally with 0.2 ml. of each dilution of the two tuberculines in two rows. The reactions are read after twenty-four and forty-eight hours. When the local reactions produced by the graded inter-dermal injections of the two preparations are comparable the brew is passed for issue.

(ii) *Heat Concentrated Synthetic Medium (H.C.S.M.) Tuberculine*.—Six adult white guinea-pigs each weighing not less than 300-450g. and sensitized three weeks previously with 0.5 mg. (moist growth from solid plants) of Myco-Tuberculosis bovine type, injected intramuscularly are used for test of each batch. The following dilutions of (a) test tuberculine and (b) standard tuberculine are used :—

1 in 500, 1 in 1000, 1 in 2000 and 1 in 4000.

The six sensitized guinea-pigs are depilated on one flank and after twenty-four hours each animal is inoculated intradermally with 0.2 ml. of each dilution of the two tuberculines in two rows. The reactions are read after twenty-four and forty-eight hours. When the local reaction produced by the graded intradermic injections of the two preparations are comparable, the test tuberculine is passed for issue. The tuberculine is dispensed in ampoules.

(iii) *Avian Tuberculine*.—Six adult fowls, with well developed wattles, sensitized at least three weeks previously by intramuscular injection with 10 mg. moist weight (from solid plants) of twenty-one days old culture of Mycobacterium tuberculosis (Avian Type) are used for potency test of each batch. In each fowl, one wattle is inoculated with 0.2 ml. of undiluted test tuberculine and the other wattle with similar quantity of undiluted standard

tuberculine. The reactions in each fowl are read after twenty-four hours and forty-eight hours and if comparable the product is passed for issue.

4. *Labelling and Storage*.—Should comply with the requirements of 'Labelling' and 'Storage' as laid down in the general monograph on 'Diagnostic Antigens'.

5. *Expiry Date*.—The date of expiry of potency shall be not more than two years from the date of manufacture when stored at 2°C to 4°C.

PART IV

GENERAL

1. For the purposes of this Schedule any test or method of testing described in the British Veterinary Codex shall be deemed to be a method approved by the Licensing Authority.

2. The Licensing Authority shall publish in the official Gazette from time to time particulars of any test or method of testing approved by him.

*SCHEDULE FF

(See rule 126-A)

Standards for ophthalmic preparations.

Part-A. Ophthalmic Solutions and suspensions

Ophthalmic Solutions and Suspensions shall—

- (a) be sterile when dispensed or when sold in the unopened container of the manufacturer, except in case of those ophthalmic solutions and suspensions which are not specifically required to comply with the test for 'Sterility' in the Pharmacopoeia.
- (b) contain one or more of the following suitable substances to prevent the growth of micro-organisms.
 - (i) Benzalkonium Chloride, 0.01 per cent (This should not be used in solutions of nitrates or salicylates).
 - (ii) Phenyl mercuric nitrate, 0.001 per cent.
 - (iii) Chlorbutanol 0.5 per cent.
 - (iv) Phenyl ethyl alcohol 0.5 per cent.

Provided that solutions used in surgery shall *not* have any preservative and be packed in single dose container.

Provided further that the Licensing Authority may in his discretion authorise the use of any other preservative or vary the concentration prescribed on being satisfied that its use affords equal guarantee for preventing the growth of micro-organisms :—

(c) be free from foreign matter.

(d) be contained in bottles made of either neutral glass or soda glass specially treated to reduce the amount of alkali released when in contact of aqueous liquids, or in suitable plastic containers which would *not* in any way be incompatible with the solutions.

*Amended under Govt. of India, Ministry of Health, F.P., W.H. and U.D. Notification No. F-1-13/69-D dt. 3-1-70.

The droppers to be supplied with the containers of ophthalmic solutions and suspensions shall be made of neutral glass or of suitable plastic material and when supplied separately shall be packed in sterile cellophane, or other suitable packings.

(c) In addition to complying with the provisions of labelling laid down in the rules the following particulars shall also be shown on the label :—

(1) *of the containers*

- (i) The statement 'Use the solution within one month after opening the container'.
- (ii) Name and concentration of the preservative, if used.
- (iii) The words 'NOT FOR INJECTION'.

(2) *of container or carton or package leaflet*

- (i) Special instructions regarding storage, wherever applicable.
- (ii) A cautionary legend reading as

"WARNING (i) if irritation persists or increases, discontinue the use and consult physician.

(ii) Do not touch the dropper tip or other dispensing tip to any surface since this may contaminate solutions."

Part-B. Ophthalmic Ointments

Ophthalmic Ointments shall—

- (a) be sterile when dispensed or when sold in the unopened container of the manufacturer.
- (b) be free from foreign matter.
- (c) in addition to complying with the provisions for labelling laid down in the rules the following particulars shall be shown on the container or carton or package leaflet—
 - (i) Special instructions regarding storage wherever applicable.
 - (ii) A cautionary legend reading

"Warning :—If irritation persists or increases discontinue the use and consult physician."

***SCHEDULE G**

[See Rule 97]

Aminopterin.

Busulphan; its salts.

Carbutamide.

Chlorambucil; its salts.

Chlorpropamide; its salts.

Cyclophosphamide; its salts.

Disodium Stilboestrol Diphosphate.

Ethosuximide.

Hydantoin, its salts, its derivatives; their salts.

Insulin.

Mannomustine; its salts.

6-Mercaptopurine; its salts.

Metformin; its salts.

Methotrexate; its salts.

Methsuximide.

Paramethadione.

Phenformin; its salts.

Phensuximide.

Thyroid gland; active principles; their salts

Tolbutamide.

Triethanomelamine; its salts.

Triethylene Thiophosphoramidate.

Troxidone.

Note.—Preparations containing the above substances are also covered by this Schedule.

*SCHEDULE H

[See Rule 65 and 97]

Allyl isopropylacetylurea.

Amidopyrine; its salts; amidopyrine sulphonates; their derivatives, their salts.

Apiol.

Arsenic, organic compounds of, for injection.

Barbituric acid; its salts; derivatives of barbituric acid, their salts, compounds of barbituric acid, its salts, its derivatives, their salts with any other substance.

Beta-aminopropylbenzene (amphetamine); its salts; its derivatives, their salts; beta-amino-isopropyl-benzene, its salts; its N-alkyl derivatives: their salts, except when present in appliances for inhalation.

Chloral Hydrate.

Cyclophosphamide; its salts.

*Amended by Government of India Notification No. F. 1-63/61-D, dated 17th July 1963.

Diaminodiphenylsulphone; its salts and derivatives.

Di-isopropylfluorophosphonate.

Dinitro cresols, their compound with a metal or a base except preparations in use in agriculture or horticulture.

Dinitronaphthols; dinitrophenols; dinitrothymols.

Disulfram.

Dithienylalmineldithienylallylamines; their salts.

Drugs coming within the purview of the Dangerous Drugs Act, 1930, and marked with an asterisk (*) in Schedule E to the Drugs and Cosmetics Rules, 1945.

Epinephrine; its salts.

Ergot, alkaloids of; their salts; their derivatives; the salts of their derivatives.

Gallamine; its salts; its quaternary compounds.

Levarterenol; its salts.

Metamizole.

Methyl phenidate; its salts.

Mustine; its salts.

Oxazolidine; its salts.

Para-amino benzene sulphonamide; its salts, derivatives of para amino benzene sulphonamide having any of the hydrogen atoms of the para amino group of the sulphonamide group substituted by another radical excluding carbutamide; their salts.

Phenylacetylurea.

Phenylbutazone; its salts; its derivatives, their salts.

Phenylcinchoninic acid; its salts; its esters; the salts of its esters.

2-(Phenyl-tolymethoxy)-ethyl dimethylamine; its salts.

3-piperidino-1-phenyl bicycloheptenyl propanol.

Polymethylene-bis-trimethylammonium salts.

Rauvolfia, alkaloids of; their salts; their esters; the salts of their esters.

Reserpine; its salts; its derivatives; their salts, the salts of its esters.

Salicylcinchoninic acid, its salts; its esters; the salts of its esters.

Sulphonals; alkyl sulphonals.

Tri-(2-chlorethyl) amine; its salts.

Note.—Preparations containing the above substances, excluding those intended for topical or external use are also covered by this Schedule, unless otherwise specified.

*SCHEDULE I

[See Rule 101 (4)]

Particulars as to proportion of poison in certain cases

Name of poison	Particulars
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Alkaloids.

Aconite, alkaloids of	The proportion of any one alkaloids of aconite that the preparation would be calculated to contain on the assumption that all the alkaloids of aconite in the preparation were that alkaloid.
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Belladonna, alkaloids of Calabar beans, alkaloids of	The same as above, with the substitution for the reference to aconite of a reference to belladonna calabar bean or such other alkaloids of the said poisons as the case may require.
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Coca, alkaloids of, Colchicum, alkaloids of	
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Ephedra, alkaloids of Ergot, alkaloids of	
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Gelsemium, alkaloids of	
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Jaborandi, alkaloids of	
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Lobelia, alkaloids of	
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Pomegrenate, alkaloids of	
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Quebracho, alkaloids of, other than the alkaloids of red quebracho	
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Sabadilla, alkaloids of, Solanaceous alkaloids not otherwise included in Column I of Schedule E. Stavesacre, alkaloids of	
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Veratrum, alkaloids of Yohimba,	
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Antimonial poisons	The proportion of antimony trioxide (Sb_2O_3) or antimony pentoxide (Sb_2O_5) that the preparation would be calculated to contain on the assumption that the antimony (Sb) in the poison had been wholly converted into antimony trioxide or antimony pentoxide as the case may be.
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Arsenic, organic compound of	The proportion of arsenic trioxide (As_2O_3) or arsenic pentoxide (As_2O_5) that the preparation would be calculated to contain on the assumption that the arsenic (As) in the poison has been wholly converted into arsenic trioxide or arsenic pentoxide as the case may be.
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Barium, salts of	The proportion of one particular barium salt which the preparation would be calculated to contain on the assumption that the barium (Ba) in the poison has been wholly converted into that salt.
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Digitalis, glycosides of; other active principles of digitalis.	The number of units of activity as defined in the Indian Pharmacopoeia contained in specified quantity of the preparation.
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*Amended by Government of India Notification No. F. 1-63/61-D, dated 17th July 1963.

<i>Name of poison</i>	<i>Particulars</i>
Hydrocyanic acid; cyanides; double cyanides of mercury and zinc.	The proportion of hydrocyanic acid (HCN) that the preparation would be calculated to contain on the assumption that the cyanides in the poison had been wholly converted into hydrocyanic acid
Insulin	The number of units of activity as defined in the Indian Pharmacopoeia contained in a specified quantity of the preparation.
Lead, compounds of, with acids from fixed oils.	The proportion of lead oxide (Pbo) that the preparation would be calculated to contain on the assumption that the lead in the Poison had been wholly converted into lead oxide.
Mercury, organic compound of	The proportion of organically combined mercury (Hg) contained in the preparation.
Nux Vomica	The proportion of Strychnine contained in the preparation.
Opium	The proportion of morphine contained in the preparation
Phenols	The proportion of phenols (added together) contained in the preparation.
Compound of phenol with a metal	The proportion of phenols (added together) that the preparation would be calculated to contain on the assumption that the compound of phenols with a metal had been wholly converted into the corresponding phenols.
Pituitary gland, the active principles of	Either (a) the number of units of activity as defined in the Indian Pharmacopoeia, contained in a specified quantity of the preparation; or (b) the proportion of pituitary gland, or of anterior or of posterior lobe of the gland as the case may be, contained in the preparation; or (c) the amount of pituitary gland, or of anterior or posterior lobe of the gland as the case may be from which a specified quantity of the preparation was obtained, together with an indication whether the amount relates to fresh or dried gland substance.
Potassium hydroxide	The proportion of potassium monoxide (K_2O) which the preparation would be calculated to contain on the assumption that the Potassium hydroxide in the preparation had been wholly converted into potassium monoxide.
Sodium hydroxide	The proportion of Sodium monoxide (Na_2O) which the preparation would be calculated to contain on the assumption that the sodium hydroxide in the preparation had been wholly converted into sodium monoxide.

<i>Name of poison</i>	<i>Particulars</i>
Strophanthus, glycosides of	The amount of Standard Tincture of Strophanthus as defined in the Indian Pharmacopoeia which possesses the same activity as a specified quantity of the preparation when assayed by the method described in the said Pharmacopoeia.
Suprarenal gland, the active principles of their salts.	<p>Either—</p> <p>(a) The proportion of suprarenal gland of the cortex or of the medulla of the gland as the case may be contained in the preparation; or</p> <p>(b) the amount of suprarenal gland or of the cortex or of the medulla of the gland as the case may be, from which a specified quantity of the preparation was obtained together with an indication whether the amount relates to fresh or dried gland substance.</p>
Thyroid gland, the active principles of	<p>Either—</p> <p>(a) the proportion of thyroid gland contained in the preparation, or</p> <p>(b) the amount of thyroid gland from which a specified quantity of the preparation was obtained together with an indication whether the amount relates to fresh or dried gland.</p>

*SCHEDULE J

(See rule 106)

Diseases and ailments (by whatever name described) which a drug may not purport to prevent or cure

1. Appendicitis.
2. Arteriosclerosis.
3. Blindness.
4. Blood Poisoning.
5. Bright's disease.
6. Cancer.
7. Cataract.
8. Deafness.
9. Diabetes.
10. Diseases and disorders of the optical system.
11. Diseases and disorders of the brain.
12. Diseases and disorders of the uterus.
13. Disorders of menstrual flow.
14. Disorders of the nervous system.

*Amended by Govt. of India Ministry of Health F.P. and U.D. Notification No. F.1-14/68-D. dated 26-10-68.

15. Disorders of the prostatic gland.
16. Dropsy.
17. Epilepsy.
18. Female diseases (in general).
19. Fevers (in general).
20. Fits.
21. Gall stones, kidney stones and bladder stones.
22. Gangrene.
23. Glaucoma
24. Goitre.
25. Heart diseases.
26. High or low blood pressure.
27. Hydrocele.
28. Hysteria.
29. Infantile paralysis.
30. Insanity
31. Leprosy.
32. Leucoderma.
33. Lockjaw.
34. Locomotor Ataxia.
35. Lupus.
36. Nervous debility.
37. Obesity.
38. Paralysis.
39. Plague.
40. Pleurisy.
41. Pneumonia.
42. Rheumatism.
43. Ruptures.
44. Sexual impotence.
45. Smallpox.
46. Sterility in women.
47. Trachoma.
48. Tuberculosis.
49. Tumours.
50. Typhoid fever.
51. Ulcers of the gastrointestinal tract.
52. Venereal diseases including syphilis, gonorrhoea, soft chancre, venereal granuloma and lympho granuloma.

SCHEDULE K

(See Rule 123)

<i>Class of Drugs</i>	<i>Extent and Conditions of Exemption</i>
1. Drugs falling under clause (b)(i) of Section 3 of the Drugs and Cosmetics Act not intended for medicinal use.	All the provisions of Chapter IV of the Act and the Rules thereunder subject to the conditions that the drug is not sold for medicinal use or for use in the manufacture of medicines and that each container is labelled conspicuously with the words "NOT FOR MEDICINAL USE".
2. Omitted	(Omitted by Government of India Notification No. F. I-56/47-D dated 16-1-1950).
*2A Quinine and other antimalarial drugs.	Persons selling the drugs by retail under arrangements made by State Government for sale and distribution of the drugs will be exempted from the requirement to take out licences for retail sale under clause (c)† of Section 18 of the Act.
@3.	
@4.	
†5. Drugs supplied by a registered medical practitioner to his own patient or any drug specific in Schedule C supplied by a registered medical practitioner at the request of another such practitioner if it is specially prepared with reference to the condition and for the use of an individual patient provided the registered medical practitioner is not (a) keeping an open shop or (b) selling across the counter or (c) engaged in the importation, manufacture, distribution or sale of drugs in India to a degree which render him liable to the provisions of Chapter IV of the Act and the Rules thereunder.	All the provisions of Chapter IV of the Act and the Rules made thereunder Subject to the following conditions : ** (1) The drugs shall be purchased only from a dealer or a manufacturer licensed under these rules and records of such purchases showing the names and quantities of such drugs together with their batch numbers and the names and addresses of the manufacturers shall be maintained. Such records shall be open to inspection by an Inspector appointed under the Act who may, if necessary, make enquiries about purchases of the drugs and may also take samples for test."

† Amended under Government of India Notification No. F. I-22/59-D. dated 9-4-1960.

* Added under Government of India Notification No. F. I-2/47-D. dated 13-2-1950.

@ Omitted by Govt. of India Ministry of Health. F.P. W.H. and U.D. Notification No. F. I-6/62-D dated 2-7-69.

† Amended under Government of India Notification No. F. I-22/59-D dated 9-4-1960.

** Amended by Min. of Health & F.W. Notification No. X-11013/3/76-D&MS. dated 19-8-78.

Class of Drugs

Exemptions and Condition of Exemption

- (2) In the case of medicine containing a substance specified in Schedule E, the following additional conditions shall be complied with.
- (a) the medicine shall be labelled with the name and address of the registered medical practitioner by whom it is supplied ;
 - (b) if the medicine is for external application, it shall be labelled with the words "Poison. For External use only" or, if it is for internal use with the dose;
 - (c) the name of the medicine or ingredients of the preparation and the quantities thereof, the dose prescribed, the name of the patient and the date of supply and the name of the person who gave the prescription shall be entered at the time of supply in register to be maintained for the purpose ;
 - (d) the entry in the register shall be given a number and that number shall be entered on the label of the container;
 - (e) the register and the prescription if any on which the medicines are issued shall be preserved for not less than two years from the date of the last entry in the register or the date of the prescription as the case may be.

5A. Drugs supplied by a hospital or dispensary maintained or supported by Government or local body or by charity or voluntary subscription.

The provisions of Chapter IV of the Act and the Rules thereunder which require them to be covered by a sale licence, subject to the following conditions :

- (1) the dispensing and supply of drugs shall be carried out by or under the supervision of a qualified person;
- (2) the premises where drugs are supplied or stocked shall be open to inspection by an Inspector appointed under the Drugs and Cosmetics Act who can, if necessary, take samples for test;
- (3) the drugs shall be stored under proper storage conditions.

*Class of Drugs**Extent and Conditions of Exemption*

- | | |
|---|---|
| 6. Medicine supplied by a veterinary hospital or by a veterinary surgeon . | All the provisions of Chapter IV of the Act and the Rules thereunder, subject to the conditions that in the case of medicine containing a substance specified in Schedule E, the container shall bear a label indicating that the medicine is intended for animal treatment. |
| 7. Quinine sulphate | <p>The provisions of sub-section (a)(i) of Section 18 of the Act to the following extent :—</p> <p>(i) the colour of the drug may be pink, owing to its being coloured with an edible pink colouring matter;</p> <p>(ii) the B. P. tests for readily carbonisable substances produce a yellow colour of an intensity about four times the colour produced with quinine sulphate conforming to the B.P. standard;</p> <p>(iii) other Cinchona alkaloids present shall not exceed six per cent; and</p> <p>(iv) the residue on incineration shall not exceed 0.14 per cent.</p> |
| Magnesium Sulphate | <p>The provisions of sub-clause (i) of clause (ii) of Section 18 of the Act to the following extent :</p> <p>Chlorides present in the salt shall not exceed 0.12 per cent in the case of the produce prepared from sea water.</p> |
| *10. The following substances which are used both as articles of food as well as drugs :— | All the provisions of Chapter IV of the Act and the Rules thereunder. |
| (i) all condensed or powdered milk whether pure skimmed or malted, fortified with vitamins and minerals or otherwise. | |
| (ii) Farex Oats, and all other similar cereal preparations whether fortified with vitamins or otherwise excepting those for parenteral use. | |
| (iii) Virol, Bovril, Chicken essence and all other similar predigested foods. | |

†Added under Government of India Notification No. F. I-19/50-DS dated 30-3-1953.

*Added under Government of India Notification No. DR/Sch. Ddk/F. I-40/54-DS, dated 27-1-1955.

<i>Class of Drugs</i>	<i>Extent and Conditions of Exemption</i>
@@ (iv) Ginger, Pepper, Cumin. Cinnamon and all other similar spices and condiments unless they are specially labelled as conforming to the standards in the Indian Pharmacopoeia or the official pharmacopoeias and official compendia of drug standards prescribed under the Act and Rules made thereunder.	
†12. Substances intended to be used for destruction of vermin or insects which cause disease in human beings or animals viz. Insecticides and Disinfectants.	The provisions of Chapter IV of the Act and the Rules thereunder which require them to be covered by a sale licence @subject to the conditions that provision of condition (17) of rule 65 of the Drugs and Cosmetics Rules, 1945 are complied with by the person stocking or selling such substances.
*13. The following household remedies, namely :— ** (1) Aspirin tablets. (2) A.P.C. tablets and powders. (3) Analgesic Balms. (4) Antacid preparations. (5) Gripe Water for use of infants. (6) Inhalers, containing drugs for treatment of cold and nasal congestion. (7) Syrups, lozenges, pills and tablets for cough. (8) Liniments for external use. (9) Skin Ointments and ointments for burns. (10) Absorbent cotton wool, bandages, absorbent gauze and adhesive plaster. (11) Castor oil, liquid Paraffin and Epsom Salt. (12) Eucalyptus Oil. (13) Tincture Iodine, Tincture Benzoin Co., and Mereurochrome solution in containers not exceeding 100 ml.	The provisions of Chapter IV of the Act and the Rules thereunder which require them to be covered with a sale licence in Form 20-A subject to the following conditions : (a) The drugs are sold only in a village having population of not more than one thousand persons and where there is no licensed dealer under the Drugs and Cosmetics Act; (b) the drugs do not contain any substance specified in Schedules E and L; (c) the drugs are sold in the original unopened containers of the licensed manufacturers; (d) when the drugs are sold under clause (a) condition 3 under "Conditions of licence", of Form 20-B shall not apply.

†Amended by Government of India Notification No. F. I-20/60-D, dated 24th January 1964.

*Added under Government of India Notification No. F. I-19/59-D, dated 13th June 1961.

**Amended by S.O. No. 2139 dated the 12-8-1972 (Govt. of India Notification No. X. 11014/12/72-D dated the 5th June, 1972).

@Added by G.S.R. 926 dated 16-7-1977 (Government of India Notification No. X. 11014/6/76-D & MS dated the 24th June, 1977).

@@Amended by G.S.R. No. 19 dated 7-1-1978 (Government of India Notification No. X. 11013/7/71-D & MS dated 15-12-1977).

<i>Class of Drugs</i>	<i>Extent and Conditions of Exemption</i>
(14) Tablets of Quinine Sulphate I.P.	
(15) Tablets of Iodochlorohydroxy quinoline—250 mg.	
†14. Mechanical Contraceptives . . .	The provisions of Chapter IV of the Act and Rules thereunder, which require them to be covered by a sale licence, @ subject to the condition that the provisions of condition (17) of rule 65 of the Drugs and Cosmetics Rules, 1945 are complied with by the person stocking or selling mechanical contraceptives.
†15. Chemical Contraceptives . . .	Family Planning Centres and other agencies authorised by the Government for the distribution of chemical contraceptives shall be exempted from the provisions of Chapter IV of the Act and Rules thereunder, which require them to be covered by a sale licence.
*16. Cosmetics	The provisions of Chapter IV of the Act and the Rules made thereunder, which require them to be covered by a licence for sale provided that the cosmetics sold, if of Indian origin, are manufactured by licensed manufacturers.
†17. Ophthalmic ointments of the Tetracycline group of drugs.	Persons authorised by the Government to distribute or sell the drugs under the National Trachoma Control Programme shall be exempted from the provisions of Chapter IV of the Act and the Rules made thereunder, which require the drugs to be covered by a sale licence.
***18.	
**19. Hair Fixers, namely macilagenous preparations containing gums, used by men for fixing beard.	The provisions of Chapter IV of the Act and the Rules thereunder.
@20. Radio Pharmaceuticals . . .	All the provisions of Chapter IV of the Act, and the Rules made thereunder.
@21. Tablets of Chloroquine Salts. . .	The provisions of Chapter IV of the Act and Rules thereunder, which require them to be covered by a sale licence, provided the drug in strip pack is sold under the Commercial Distribution scheme of the National Malaria Eradication Programme and duly labelled as "National Malaria Eradication Programme—Ministry of Health and Family Welfare, Government of India."

†Added under Government of India Notification No. F. 1-39/61-D, dated 23rd March, 1964.

*Added under Government of India Notification No. 1-36/64-D, dated 17th August, 1964.

†Added under Government of India Notification No. 1-21/63-D, dated 4th January, 1965.

**Added by S.O. No. 2139 dated 12-8-1972 (Government of India Notification No. X. 11014/12/72-D, dated the 5th June, 1972).

@Added under G.S.R. No. 926 dated 16-7-1977 (Government of India Notification No. X. 11014/6/76-D&MS, dated 24-6-1977).

***Deleted under G.S.R. No. 1594 dated 13-11-76 (Government of India Notification No. X. 11014/4/76-D&MS, dated 28-10-1976).

@Added under G.S.R. No. 697(E) dated 11-11-1977 (Government of India Notification No. X. 11014/1/77-D&MS, dated 11-11-1977).

*SCHEDULE L

[See Rules 65(9) and 97]

Adrenocorticotrophic hormone (ACTH),

Androgenic, anabolic, oestrogenic, and progestational substances, the following—

Benzoestrol.

Derivatives of stilbene, dibenzyl or naphthalene, with oestrogenic activity; their esters.

Steroid compounds with androgenic or anabolic, oestrogenic or progestational activity; their esters.

Antibiotics specified below, their salts and derivatives; and salts of their derivatives.

Bacitracin.

Carbomycin.

Chloramphenicol.

Chlortetracycline.

Colimycin.

Dihydrostreptomycin.

Erythromycin.

Framycetin.

Gramicidin.

Griseofulvin.

Kanamycin.

Neomycin.

Novobiocin.

Nystatin.

Oleandomycin.

Oxytetracycline.

Penicillin.

Paramomycin.

Polymyxin.

Spiramycin.

Streptomycin.

Tetracycline.

Tyrothricin.

Vancomycin.

Viomycin.

Amitriptylline; its salts.

Antihistamine substances, the following; their salts, their derivatives, salts of their derivatives—

Antazoline.

Bromazine.

Bucazine.

Chlorcyclizine.

Diphenhydramine.

Diphenylpyraline.

3-Di-N-butyl-aminoethyl-4, 5, 6-trihydroxyphthalide.

Isotipendyl -(N-dimethylaminoisopropyl thiophenyl pyridylamine).

Meclazine.

Phenindamine.

Pheniramine.

Promethazine.

Propenpyridamine.

Thenalidine; [1-Methyl-4-amino-N-Phenyl-N' (2-Thenyl)-Piperidine] Tartrate.

Substances being tetra-substituted N-derivatives of ethylene diamine or propylene diamine.

Azapetine its salts.

Benactyzine, its salts.

Bendrofluazide.

Benzthiazide.

Brethylum Tosylate.

Captodine; its salts.

Chlorisondamine Chloride.

Chlormezanone.

Chlorpromazine; its salts.

Chlorprothixene.

Chlorthiazide.

Citrated Calcium Carbimide.

Clidinium Bromide.

Cortisone, hydrocortisone, prednisone, prednisolone, triamcinolone and dexamethazone; their esters; their derivatives and esters of their derivatives.

Cyclopentthiazide.

Dithiazinine Iodide.

Ethionamide.

Glutethimide; its salts.

Guanethidine.

- Hexadimethrine Bromide.
Hexocyclium methyl Sulphate.
Hydrochlorthiazide.
Imipramine; its salts.
Hydroflumethiazide.
Hydroxyzine; its salts.
Imipramine; its salts.
Iron preparations for parenteral use.
Isocarboxacid.
Isonicotinic acid hydrazide and other hydrazine derivatives of isonicotinic acid: their derivatives; their salts.
Isoxsuprine.
Meprobamate.
Methaqualone; its salts.
Methylchlothiazide.
Methylpentynol; its esters and other derivatives.
Metronidazole.
Nialamide; its salts.
Oxytocin, prepared from the pituitary body or by synthesis.
Para-aminosalicylic acid; its salts; its derivatives, their salts.
Pempidine; its salt.
Pecazine; its salt.
Phenelzine; its salts.
Phenothiazine, derivatives of and salts of its derivatives not otherwise specified in this Schedule.
Phenynamidol; its salts.
Pituitary gland, the active principles of, not otherwise specified in this Schedule, and their salts.
Pivazide.
Polythiazide.
Promazine; its salts.
Pyrvinium; its salts.
Sorbide Nitrate.
Spiranolactone.
Thiopropazate; its salts.
Tranlycypromine; its salts.
Trimeprazine; its salts.
Visopressin, prepared from the pituitary body or by synthesis.

Note.—1. Preparations containing the above substances excluding those intended for topical, or external use, are also covered by this Schedule.

2. The inclusion of any substance in Schedule L does not imply or convey that such substance is exempted from the provisions of rule 30-A of the Drugs and Cosmetics Rules.

***SCHEDULE M**

[See Rules 71, 71-A and 76]

(1) *Requirements of Factory premises*

(A) *Location and surroundings.*—The factory shall be situated in a place which shall not be adjacent to an open sewage, drain, public lavatory or any factory which produces a disagreeable or abnoxious odour or fumes or large quantities of soot, dust or smoke. The factory shall be located in a sanitary place, remote from filthy surroundings.

(B) *Buildings.*—The buildings used for the factory shall be constructed so as to permit of production under hygienic conditions. They shall conform to the conditions laid down in the Factories Act, 1948 (63 of 1948). The part of the building used for manufacture shall not be used as a sleeping place and no sleeping place adjoining to it shall communicate therewith except through open air or through an intervening open space.

The walls of the room in which manufacturing operations are carried out shall, up to a height of six feet from the floor, be smooth, water-proof and must be capable of being kept clean. The flooring shall be smooth, even and washable and shall be such as not to permit of retention or accumulation of dust. There shall be no chinks or crevices in the walls or floor.

(C) *Water Supply.*—The water used in manufacture shall be pure and of drinkable quality, free from pathogenic micro-organisms.

(D) *Disposal of Waste.*—Waste water and other residues from the laboratory which might be prejudicial to the workers or to public health shall be disposed of after suitable treatment to render them harmless.

(E) *Health, Clothing and Sanitary requirement of the Staff.*—All workers shall be free from contagious or abnoxious disease. Their clothing shall consist of a white or coloured uniform suitable to the nature of work and the climate, and shall be clean. Adequate facilities for personal cleanliness, such as clean towels, soap and hand scrubbing brushes shall be provided separately for each sex. The workers shall be required to wash and change into clean footwear before entering the rooms where the manufacturing operations are carried on. The workers shall also be required to wear either a clean cap or a suitable head gear so as to avoid any possibility of contamination by hair or perspiration. For those engaged in filling and sealing of containers for parenteral preparations, suitable cotton masks should be provided to cover the nostrils and mouth during work.

(F) *Medical Services.*—The manufacturer shall provide :

(1) Adequate facilities for First Aid.

(2) Medical inspection of workers at the time of employment and periodically check up thereafter at least once a year.

(3) Facilities for vaccination and inoculation against the enteric or any other epidemic group of diseases.

(4) Adequate precautions for safeguarding the head of the workers, including measures to avoid industrial accidents or diseases.

(G) Working benches shall be provided for carrying out operations such as filling, labelling, packing etc. Such benches shall be fitted with smooth, impervious tops capable of being washed.

(H) In factories where operations involving the use of containers, such as, bottles, vials, jars, ampoules, are conducted, there shall be adequate arrangements separated from the manufacturing operations for washing, cleaning and drying such containers with suitable equipment for the purpose. Sterilising facilities where necessary should also be provided.

(2) *Requirements of Plant and Equipment*

(A) The following equipment is recommended, for the manufacture of Ointments, Emulsion or Lotions and Suspensions :

1. Mixing tanks.
2. Kettle, steam, gas or electrically heated.
3. A suitable power-driven mixer.
4. Storage tanks or pots.
5. A colloid mill or a suitable emulsifier.
6. A tripleroller mill or an ointment mill.
7. Liquid filling equipment.
8. Jar or tube filling equipment.

An area of 30 square metres is recommended for the basic installations.

(B) The following equipment is recommended for manufacture of Syrups, Elixirs and Solutions :

1. Mixing and storage tanks.
2. Portable mixer.
3. Filter press or other suitable filtering equipment, such as metafilter or sparklet filter.
4. Vacuum or gravity filter.
5. Water still or Deioniser.

An area of 30 square metres is recommended for the basic installations.

(C) *Equipment for the manufacture of Pills and Compressed Tablets including Hypodermic Tablets.*—For efficient operation the tablet production department shall be divided into three distinct and separate Sections—

- (a) Granulating Section :
- (b) Tableting Section :
- (c) Coating Section :

The following equipment is recommended in each of the three Sections.

(a) *Granulating Sections :*

1. Disintegrator.
2. Powder Mixer.
3. Mass Mixer.

4. Granulator.
5. Ovens, thermostatically controlled.

(b) *Tableting Section :*

1. Tablet machine, single punch or rotary.
2. Pill machine.
3. Punch and dies storage cabinet.
4. Tablet counter.

The Tableting Section shall be free from dust and floating particles. For this purpose, it is desirable that each tablet machine is connected either to an exhaust system or isolated into cubicles.

(c) *Coating Section :*

1. Jacketed kettle, steam, gas or electrically heated for preparing solution.
2. Coating pan.
3. Polishing pan.
4. Heater and exhaust system.

The coating section shall be made dust-free and suitable exhaust provided to remove excess powder and the fumes resulting from solvent evaporation. An area of 30 square metres for each of the above three Sections is recommended for basic installations.

The manufacture of Hypodermic Tablets shall be conducted under aseptic conditions in a separate air-conditioned room, the walls of which shall be smooth and washable. The granulations, tableting and packing shall be done in this room.

(D) The following equipment is recommended for the manufacture of Powders.

1. Disintegrator.
2. Mixer.
3. Sifter
4. Stainless steel vessels and scoops of suitable material.
5. Filling equipment.

In case of operations involving floating particles of fine powder or dust a suitable exhaust system shall be provided. Workers should be provided with suitable masks during operation.

An area of 30 square metres is recommended to allow for the basic operations. Where the actual powdering is to be done on the premises an additional room shall be provided for the purpose.

(E) The following equipment is recommended for filling of Hard Gelatin Capsules.

1. Mixing and blending equipment.
2. Capsule filling units.
3. Capsule counters.

An area of 20 square metres is recommended for the basic installations for capsules filling. The room shall be air conditioned and also dehumidified wherever necessary.

In case of operations involving floating particles of fine powder or dust a suitable exhaust system shall be provided.

(F) The following equipment is recommended for the manufacture of Surgical Dressings other than Absorbent Cotton Wool :

1. Rolling machine.
2. Trimming machine.
3. Cutting equipment.
4. Folding and pressing machine for gauze.
5. Mixing tanks for processing medicated dressings.
6. Hot air drying ovens.
7. Steam steriliser or dry heat steriliser.

An area of 30 square metres is recommended to allow for the basic installations. In case medicated dressings are to be manufactured another room with an area of 30 square metres shall be provided.

(G) The following equipment is recommended for manufacture under aseptic conditions of Eye-Ointments, Eye-Drops, Eye-Lotions and other preparations for external use :

1. Hot air oven electrically heated with thermostatic control.
2. Kettle, gas or electrically heated with suitable mixing arrangement.
3. Colloid mill or ointment mill.
4. Tube filling equipment.
5. Mixing and storage tanks of stainless steel or of other suitable material.
6. Sintered glass funnel, Seitz filter or filter candle.
7. Liquid filling equipment.
8. Autoclaves.

An area of 25 square metres is recommended for the basic installations. The manufacture and filling shall be carried out in an air-conditioned room under aseptic conditions. The room shall be further dehumidified if preparations containing antibiotics are manufactured.

(H) The following equipment is recommended for manufacture of Pessaries and Suppositories :

1. Mixing and pouring equipment.
2. Moulding equipment.

An area of 20 square metres is recommended to allow for the basic installations.

In case of pessaries manufactured by granulation and compression, if the licensee does not have a tablet section, a separate area of 30 square metres and the following equipment is considered necessary.

1. Mixer.
2. Granulator.
3. Drier.
4. Compressing machine.
5. Pessary and tablet counter.

(I) The following equipment is recommended for manufacture of Inhalers and Vitrallae :

1. Mixing equipment.
2. Graduated delivery equipment for measurement of the medicament.
3. Sealing equipment.

An area of 20 square metres is recommended for the basic installations.

(J) The following equipment is recommended for the repacking installations of drugs and Pharmaceutical Chemicals :

1. Sifter.
2. Stainless steel scoops and vessels.
3. Weighing and measuring equipment.
4. Filling equipment.

An area of 30 square metres is recommended for basic packing operations. In case of operations involving floating particles of fine powder or dust a suitable exhaust system should be provided.

(K) *Requirements for the manufacture of Parenteral Preparations.*—The whole process of the manufacture of parenteral preparations may be divided into the following separate operations.

- (a) *Preparations of the container.*—This includes cutting, washing, drying and sterilisation of ampoules or vials prior to filling.
- (b) *Preparation of solution.*—This includes preparation and filtration of solution.
- (c) *Filling and sealing.*—This includes filling and sealing of ampoules or filling and capping of vials.
- (d) Sterilisation.
- (e) Testing.

The following basic hygienic requirements shall be complied with :

- (1) Strict sanitation shall be maintained throughout the entire plant in order to prevent contamination and to keep out pyrogens. Masks and overalls shall be worn wherever necessary.
- (2) The preparation room where the solutions are prepared shall be tiled and kept scrupulously clean. This room shall be air-conditioned.
- (3) The filling and sealing rooms shall likewise be air-conditioned under positive pressure with air locks provided to prevent the

entry of air from outside. The walls and floors shall be tiled so as to permit their being sprayed and washed with an anti-septic solution. The benches shall preferably have stainless steel or laminated plastic tops capable of being washed.

- (4) In the room provided for aseptic filling and sealing, a sufficient number of sterilising lamps shall be mounted over the benches and in the air lock leading to the room to prevent contamination.
- (5) A separate room shall be provided for sterilisation, testing (for leaks and floating particles) and drying.
- (6) Separate arrangements for labelling and packing.
- (7) Finished products shall be stored in a separate cool and dry area.

The following equipment is recommended :

Manufacturing Area :

1. Storage equipment for ampoules and vials.
2. Ampoule washing and drying equipment.
3. Dust proof storage cabinets.
4. Water Still.
5. Mixing and preparation tanks or other containers.

The tanks or containers shall be made of either glass or such material as will not react with the liquid.

6. Filtering equipments such as filter press or sintered glass funnel.
7. Autoclave.
8. Hot Air Steriliser.

Filling and sealing room :

9. Benches for filling and sealing.
10. Filling and sealing unit.

Aseptic filling and sealing room :

11. Bacteriological filters such as Seitz filter, filter candles or sintered glass filters.
12. Filling and sealing unit.

General Room :

13. Inspection table.
14. Leak testing equipment.
15. Labelling and packing benches.
16. Storage equipment including cold storage and refrigerators, if necessary.

An area of 60 square metres partitioned into suitably sized cubicles, is recommended for the basic installations.

Note I.—The above requirements of Schedule M are subject to modifications at the discretion of the Licensing Authority if he is of the opinion that having regard to the nature and extent of the manufacturing operations it is necessary to relax or alter them in the circumstances of a particular case.

**Note II.*—Schedule M gives equipments and space required for certain categories of drugs only. There are, in addition, other categories of drugs such as basic drugs, miscellaneous pharmaceuticals such as Ferri et Ammonii Citras, Potassium Citras, Glycerine, Paraffins, Oxygen gas, Disinfectant fluids, mechanical contraceptives, surgical cotton and tinctures which are not listed in this Schedule. The licensing authority shall, in respect of such categories of drugs, have the discretion to examine the adequacy or otherwise of factory premises, space, plant machinery and other requisites, having regard to the nature and extent of the manufacturing operations involved and direct the manufacturer to carry out necessary modifications in them and on the modification having been made, approve of the manufacture of such categories of drugs. Any drugs so permitted to be manufactured by the Licensing Authority shall be deemed to be an additional category of drug for the purpose of this Schedule and sub-rule (5) of rule 69.

† SCHEDULE N

(See rule 64(1))

List of minimum equipment for the efficient running of a Pharmacy :—

I. Entrance.—The front of a pharmacy shall bear an inscription “Pharmacy”.

II. Premises.—The premises of pharmacy shall be separated from rooms for private use. The premises shall be wellbuilt, dry, well-lit and ventilated and, of sufficient dimensions to allow the goods in stock, especially medicaments and poisons to be kept in a clearly visible and appropriate manner. The areas of the Section to be used as dispensing department shall be not less than 6 sq. meters for one pharmacist working therein with additional 2 sq. meters for each additional pharmacist. The height of the premises shall be at least 2.5 metres.

The floor of the Pharmacy shall be smooth and washable. The walls shall be plastered or tiled or oil painted so as to maintain smooth, durable and washable surface devoid of holes, cracks and crevices.

A Pharmacy shall be provided with ample supply of good quality water.

The dispensing department shall be separated by a barrier to prevent the admission of the public.

III. Furniture and apparatus.—The furniture and apparatus of a Pharmacy shall be adopted to the uses for which they are intended and correspond to the size and requirements of the establishment.

*Added under Govt. of India, Ministry of Health, F.P., W. H. and U. D. Notification No. F. 1-113/69-D, dated 23-12-69.

†Amended by S. O. No. 2139 dated 12-8-1972 (Govt. of India Notification No. X 11014/12/72-D dated the 5th June, 1972).

Drugs, chemicals, and medicaments shall be kept in a room appropriate to their properties and in such special containers as will prevent any deterioration of the contents or of the contents of containers kept near them. Drawers, glasses and other containers used for keeping medicaments shall be of suitable size and capable of being closed tightly to prevent the entry of dust.

Every container shall bear a label of appropriate size, easily readable, with names of medicaments as given in the Pharmacopoeias.

A Pharmacy shall be provided with a dispensing bench, the top of which shall be covered with washable and impervious material like stainless steel laminated plastic, etc.

A Pharmacy shall be provided with a cupboard with lock and key for the storage of poisons and shall be clearly marked with the word "POISON" in red letters on a white background.

Containers of all concentrated solutions shall bear special label or marked with the words "To be diluted".

A Pharmacy shall be provided with the following minimum apparatus and books necessary for making of official preparations and prescriptions :—

Apparatus :—

- Balance, dispensing, sensitivity 30 mg.
- Balance, counter, capacity 3 kgm, sensitivity 1 gm.
- Beakers, lipped, assorted sizes.
- Bottles, prescription, ungraduated assorted sizes.
- Corks assorted sizes and tapers.
- Cork extractor.
- Evapoarting dishes, porcelain.
- Filter paper.
- Funnels, glass.
- Litmus paper, blue and red.
- Measure glasses cylindrical 10 ml., 25 ml., 100 ml. and 500 ml.
- Mortars and pestles, glass.
- Mortars and pestles, wedgwood.
- Ointment posts with bakelite or suitable caps.
- Ointment slab, Porcelain.
- Pipettes, graduated, 2 ml. 5 ml. and 10 ml.
- Ring, stand (retort) iron, complete with rings.
- Rubber stamps and pad.
- Scissors.
- Spatulas, rubber or vulcanite.
- Spatulas, stainless steel.
- Spirit lamp.

Glass stirring rods.

Thermometer, 0° to 200°C.

Tripod stand.

Watch glasses.

Water bath.

Water distillation still in case Eye drops and Eye lotions are prepared.

Weights, Metric, 1 mg. to 100 gm.

Wire Gauze.

*Pill finisher, boxwood.

*Pill machine.

*Pill Boxes.

*Suppository mould.

Books :

The Indian Pharmacopoeia (Current Edition). National Formulary of India (Current Edition).

The Drugs and Cosmetics Act, 1940.

The Drugs and Cosmetics Rules, 1945.

The Pharmacy Act, 1948.

The Dangerous Drugs Act, 1930.

IV. General Provisions.—A Pharmacy shall be conducted under the continuous personal supervision of a Registered Pharmacist whose name shall be displayed conspicuously in the premises.

The Pharmacist shall always put on clean white overalls.

The premises and fittings of the Pharmacy shall be properly kept and everything shall be in good order and clean.

All records and registers shall be maintained in accordance with the laws in force.

Any container taken from the poison cupboard shall be replaced therein immediately after use and the cupboard locked. The keys of the poison cupboard shall be kept in the personal custody of the responsible person.

Medicaments when supplied shall have labels conforming to the provisions of laws in force.

NOTE:—

The above requirements are subject to modifications at the discretion of the Licensing Authority, if he is of opinion that having regard to the nature of drugs dispensed, compounded or prepared by the licenser, it is necessary to relax the above requirements or to impose additional requirements in the circumstances of a particular case. The decision of the Licensing Authority in that regard shall be final.

*These items are to be provided only by those who intend to dispense pills or suppositories & the case may be.

***SCHEDULE O**

[See Rule 126]

A. Provisions applicable to Black Disinfectant Fluids (Emulsifying).

Black Disinfectant Fluids (Emulsifying) is homogenous solution prepared from coaltar acid fractions with the aid of a suitable emulsifier. It shall contain not less than 40 per cent w/w of Coal Tar Acids, phenolic compounds, and Coal Tar Oils and shall have a phenol co-efficient not less than 18 (Grade 1), 10 (Grade 2), or 5 (Grade 3). It shall not contain quaternary ammonium compounds, mercury salts, kerosene or other non-phenolic petroleum distillates.

Stability after dilution—

Preparation of artificial hard water—40 ml of N/1 Hydrochloric Acid is neutralised with a slight excess of calcium carbonate and filtered. The filtrate is diluted to 1,000 ml. with distilled water, 10 parts of the solution is further diluted to 100 parts with distilled water.

Procedure.—To 475 ml and 495 ml respectively of the artificial hard water contained in each of two 500 ml. stopper measuring cylinders at temperature between 15°C and 45°C 25 ml and 5ml respectively of the sample are added and emulsified by inverting and righting the cylinder 30 times. The cylinders are maintained at a temperature between 15°C and 45°C for 6 hours, and examined by reflected light. Not more than a trace of separation shall occur at top and bottom.

**Assay for Coal Tar Acids, Coal Tar Oils and Phenolic Compounds—
For Black Disinfectant Fluids—**

10 g of the sample accurately weighed is shaken with 5 ml of saturated solution of sodium chloride and transferred to a 250 ml separating funnel. 50 ml. of solvent ether, precooled to 15°—20°C, is added, the mixture shaken vigorously and allowed to stand. 3—4 ml. of Ethyl Alcohol may, if necessary, be added to hasten separation into two layers. The aqueous layer is run off into a second separating funnel (150 ml) and extracted with 2 more portions of 20 ml. each of solvent ether. The ether extracts are collected together and washed twice with 25 ml. of distilled water each time and the aqueous portions are rejected. The ether extract is finally collected into a tared 250 ml. wide mouthed flask or beaker (containing a few glass beads) through a layer of anhydrous sodium sulphate. The separating funnel is washed with about 20 ml. of solvent ether and this is collected into the flask or beaker through the same layer of anhydrous sodium sulphate. The ether is distilled off and the residue dried to constant weight on a steam bath. From the weight of the residue, the percentage of coal tar acids and oils is calculated.

Assay for Phenol Co-efficient—

All apparatus used in the test must be scrupulously clean and sterile immediately before use.

Special Apparatus : Inoculating 100p.—4mm in internal diameter formed at the end of a length of 28 S.W.G. (0.376 mm) wire of platinum or platinum iridium alloy measuring 38 mm from the loop to the holder.

*Added under Government of India Notification No. F. 1-20/60-D, dated 24th January, 1964.

e loop is bent at such an angle as will facilitate its removal vertically from the surface of the liquid.

Incubator—Maintained at $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$.

Constant temperature water bath— 17°C and 18°C .

Dropping Pipette—To deliver 0.2 ml in about 5 drops.

Broth tubes— 12.5×2 cm. hard glass test tubes.

Medication tubes— 12.5×2 cm. test tubes.

Culture Medium—20 g of Lab. Lemco, 20 g of peptone and 10 g of sodium chloride are dissolved in 1,000 ml of distilled water. The solution is boiled for 30 minutes, cooled and made up to 1,000 ml with freshly distilled and cooled distilled water. 25 ml of this broth is titrated at 30°C with N/10 sodium hydroxide solution, using 0.1 ml of 0.5 per cent. phenolphthalein solution as indicator. By calculation from this titration the bulk of the broth shall be neutralised with N/1 sodium hydroxide solution and brought to boil to precipitate phosphates, and filtered while hot. The broth is adjusted to pH 7.6 by the addition of N/1 Hydrochloric acid, using a comparator with phenol red as the indicator, and sterilized by filtering in an autoclave. After cooling, the broth is filtered and distributed in 5 ml. quantities into sterile broth tubes and sterilized in an autoclave at 121°C (15 pounds per square inch) for 10 minutes. The final reaction of the broth is between pH 7.3 and pH 7.5.

Culture—Cultures of *Salmonella Typhi* (786) *Bacterium Typhosum* shall be used. This culture shall be maintained in the laboratory, with weekly subculture on a nutrient Agar Slope (made by dissolving 2.5 per cent agar in the broth prepared as above) incubating the slope for the 24 hours at 37°C and then keeping it cool preferably below 22°C . A little of growth from a stock agar slope culture is transferred to a 5 ml broth tube and incubated at 37°C for 24 hours. For subsequent generations a standard loopful of the culture is transferred to a fresh broth tube and incubated at 37°C before. Only cultures which have been grown for 24 hours at 37°C as before and only those between the third and fourteenth generation shall be used.

Standard Phenol—A 5 per cent. w/v solution in sterile distilled water of chemically pure phenol having a crystallising point of not less than 6°C is prepared. Test dilutions are prepared from this stock solution containing 1 g of phenol in each 95, 100, 105, 110 and 115 ml of solution. These dilutions shall be used within a week of preparation.

Test Solution of Disinfectant.—The sample is mixed thoroughly, 5 ml is drawn in a capacity pipette and discharged into about 480 ml of sterile distilled water in a 500 ml glass-stoppered sterile measuring cylinder, and the pipette rinsed in the clear liquid. The solution is diluted to 500 ml. and mixed thoroughly by a cork screw motion. Serial test dilutions are prepared by making up 5 or 20 ml amounts of this solution to the appropriate volume, with distilled water. The dilutions are made in arithmetical series, spaced in units of 50 i.e., 1 in 100, 1 in 150, 1 in 200 and so on to 1 in 400, and in units of 100 thereafter.

Procedure—5 ml of each of the chosen dilutions of the disinfectant are measured into four sterile medication tubes, and placed in a suitable rack

alongside the 24 hours broth culture and fifth tube containing 5 ml of of the standard phenol dilution in a water-bath maintained at 17°C 18°C. When the content of the tubes and the culture have reached the temperature of the waterbath, 0.2 ml. of the culture is added to the first tube and shaken gently. After 30 seconds the second tube is subcultured and so on until the fifth tube has been inoculated. 30 seconds after the last inoculation, i.e., 2.5 minutes after the first, the first tube is shaken and one standard loopful of the mixture is subcultured in a 5 ml tube of broth. The procedure is repeated at 30 seconds intervals until the whole cycle has been repeated four times, that is until each medication tube has been subcultured after 2.5, 5, 7.5 and 10 minutes disinfection time. The broth subculture tubes are incubated at 37°C for not less than 48 hours and not more than 72 hours. The presence or absence of growth in each tube is recorded. If there is any evidence of contamination in broth tube the whole test is to be discarded and repeated.

Calculation of the Phenol Co-efficient.—The Phenol co-efficient is calculated by dividing the dilution of disinfectant, which shows life after 2.5 and 5 minutes, but not after 7.5 and 10 minutes, by that dilution of phenol which shows the same end point. The following is typical test result.

Disinfectant	Dilution	Time culture was exposed to action of disinfectant (in minutes)			
		2½	5	7½	10
A	1 in 1000	—	—	—	—
A	1 in 1100	+	—	—	—
A	1 in 1200	+	+	—	—
A	1 in 1300	+	+	+	—
Control Phenol 1 in 105		+	+	—	—

(+ = Growth — = No growth)

$$\text{Phenol Co-efficient} = \frac{1200}{105} = 11.4$$

NOTE—The reagents and solution employed in the above test shall comply with the specification laid down in the Indian Pharmacopoeia, unless otherwise specified.

Stability.—Black Disinfectant Fluid (Emulsifying) shall remain stable for at least six months from the date of manufacture.

Storage.—Black Disinfectant Fluid (Emulsifying) shall be stored in mild steel, tinned mild steel or other suitable containers. It shall not be stored in containers made of galvanised iron.

Labelling.—In addition to the labelling provisions under the Drugs and Cosmetic Rules the label on the container shall state (i) the name of the product, (ii) the name and address of the manufacturer, (iii) grade and Phenol Co-efficient of the product, (iv) the date of manufacture, (v) the date before which the product shall be used, (vi) the quantity present in the container and (vii) the method of use.

B. Provision Applicable to White Disinfectant Fluid—

White Disinfectant Fluid is a finely dispensed, stabilized emulsion comprising coal tar acids and coal tar oils. It shall contain not less than 25 per cent of w/w of Coal Tar acids, Phenolic compounds and Coal Tar oils and shall have phenol co-efficient of not less than 18 (Grade I), 10 (Grade 2) or 5 (Grade 3).

Stability after dilution—

Preparation of artificial sea water—27.0 g of sodium chloride and 5.0 g of magnesium sulphate are dissolved in sufficient water to produce 1000 ml. The solution is filtered before use.

Procedure—To 475 and 495 ml respectively of the artificial sea water contained in each of two 500 ml stoppered measuring cylinders and a temperature between 15°C and 45°C, 25 and 5 ml respectively of the sample is added and emulsified by inverting and righting the cylinders 30 times. The emulsion is maintained at a temperature between 15°C and 45°C for 6 hours and examined by reflected light. Not more than a trace of separation shall occur at top and bottom.

Assay for Coal Tar Acid, Phenolic Compounds and Coal Tar Oils—

Determined by the method given under 'Black Disinfectant Fluids (Emulsifying)', subject to the modification that 10 g of the sample is shaken with 5 ml of 1 : 1 sulphuric acid before the addition of ether.

Stability—White Disinfectant Fluid shall remain stable for at least 3 months from the date of manufacture.

Storage—White Disinfectant Fluid shall be stored in mild steel, tinned mild steel or other suitable containers. It shall not be stored in containers made of galvanized iron.

Labelling—In addition to the labelling provisions under the Drugs and Cosmetics Rules the label on the container shall state (i) the name of the product, (ii) the name and address of the manufacturer, (iii) grade and phenol Co-efficient of the product, (iv) the date of manufacture, (v) the date before which the product shall be used, (vi) the quantity present in the container, and (vii) the method of use.

*SCHEDULE P

[See rule 96]

Life period of drugs

Name of the Drug	Period in months in which the drug is expected to retain its potency under the conditions of storage notified by the Licensing Authority specified in Sub-rule 59 of rule 59
1	2
Adrenaline for Infection	12 months
Anti-haemophillic Human Globulin	12 months.
ANTIBIOTICS	
Penicillin Crystalline	24 months.
Penicillin Oil and Wax	18 months.
Procaine Penicillin G.	36 months.
Penicillin Tablets and Lozenges	12 months.
Penicillin Ointments	12 months.
Potassium Phenoxymethyl Penicillin Tablets	18 months.
Benzathine Penicillin G.	36 months.
Streptomycin Sulphate or Hydrochloride	48 months.
Dihydrostreptomycin Sulphate or Hydrochloride	48 months.
Streptomycin and Dihydrostreptomycin Sulphate or Hydrochloride	48 months.
Streptomycin or Dihydrostreptomycin Tablets	24 months.
Streptomycin or Dihydrostreptomycin Ointment	24 months.
Chloramphenicol Capsules and Tablets	60 months.
Chloramphenicol Palmitate	48 months.
Chloramphenicol Palmitate Oral Suspension	48 months.
Chlortetracycline Hydrochloride (Crystalline)	60 months.
Chlortetracycline Hydrochloride Capsules	60 months.
Chlortetracycline Hydrochloride Tablets	24 months.
Chlortetracycline Hydrochloride Ointments	24 months.
Tetracycline Hydrochloride	36 months.
Tetracycline	24 months.
Tetracycline Hydrochloride for intramuscular use	36 months.
Tetracycline Hydrochloride Capsules	36 months.
Tetracycline Capsules	24 months.
Tetracycline or Tetracycline Hydrochloride Tablets	24 months.
Oxytetracycline Hydrochloride	36 months.

*Added under Government of India Notification No. 1-7/62-D, dated 11th May, 1964.

1	2
Oxytetracycline Hydrochloride Capsules	36 months.
Oxytetracycline Hydrochloride Tablets	24 months.
Bacitracin Powders	18 months.
Bacitracin or Zinc Bacitracin (Tablets)	12 months.
Bacitracin or Zinc Bacitracin Lozenges	12 months.
Demethyl Chlortetracycline Hydrochloride	36 months.
Demethyl Chlortetracycline Hydrochloride Capsules	36 months.
Arsenicals like Neoarsphenamine, Sulpharsphenamine and Tryparsamide	60 months.
Chorionic Gonadotrophin and injection	24 months.
Cobra Venom in solution	3 months.
Concentrated Human Red Blood Corpuscles	12 hours
Corticotrophin	24 months.
Dextran Injection	60 months.
Dextran Sulphate Injection	24 months.
Ergonovine Maleate Injection	24 months.
Heparin Injection	36 months.
Human Fibrin Foam	36 months.
Human Fibrinogen	36 months.
Human Thrombin	36 months.

INSULIN PREPARATIONS

Globulin Zinc Insulin Injection	24 months.
Insulin Injection	24 months.
Insulin Zinc Suspension	24 months.
Isophane Insulin Injection	24 months.
Protamine Zinc Insulin Injection	24 months.
Liquid Extract of Ergot	12 months.
Liver Extract Crude Injection	24 months.

NORMAL HUMAN PLASMA

Liquid Plasma	24 months.
Frozen Plasma	60 months.
Dried Plasma	60 months.
Pituitary Posterior Injection	18 months.
Oxytocin Injection	24 months.
Vasopression Injection	24 months.
Protein Hydrolysate	12 months.
Dried Normal Human Serum Albumin	60 months.
Liquid Normal Human Serum Albumin	60 months.

SCHEDULE P—*Contd.*

1	2
PERTUSSIS IMMUNE HUMAN SERUM	
Liquid Serum	12 months.
Lyophilised Anti-Snake Venom Serum	60 months.
Lyophilised Schick Test Toxin and Control	60 months.
Sterilised Surgical ligature and Suture	60 months.
Thrombin (Bovine origin)	36 months.
Alum precipitated Diphtheria Toxoid	24 months.
Alum precipitated Diphtheria and Tetanus Toxoid	24 months.
Alum Precipitated Diphtheria and Tetanus Toxoid and Pertussis Vaccine combined	18 months.
Alum Precipitated Tetanus Toxoid	24 months.
Aluminium Hydroxide Adsorbed Diphtheria Toxoid	24 months.
Aluminium Hydroxide Adsorbed Diphtheria and Tetanus Toxoid	24 months.
Aluminium Hydroxide Adsorbed Diphtheria and Tetanus Toxoid & Pertussis Vaccine combined	18 months.
Aluminium Hydroxide Adsorbed Tetanus Toxoid	24 months.
Aluminium Phosphate Adsorbed Diphtheria Toxoid	24 months.
Aluminium Phosphate Adsorbed Diphtheria and Tetanus Toxoid	24 months.
Aluminium Phosphate Adsorbed Diphtheria Toxoid, Tetanus Toxoid and Pertussis Vaccine combined	18 months.
Diagnostic Diphtheria Toxins (Schick Test)	12 months.
Diphtheria Toxoid	24 months.
Inactivated Diagnostic Diphtheria Toxin	12 months.
Old Tuberculin	60 months.
Tetanus Toxoid	24 months.
Tuberculin PPD	60 months.
Vaccine Lymph	6 months when stored at 0°C and 3 months when stored between 0° to 5°C and 14 days when stored below 10°C.

OTHER VACCINES

Alum precipitated Pertussis Vaccine	18 months.
B.C.G. Vaccine	14 days.
Cholera Vaccine	18 months.

SCHEDULE P—*contd.*

1	2
Plague Vaccine.	36 months.
Rabies Vaccine	6 months.
Typhoid Vaccine	18 months.
Typhoid and Paratyphoid Vaccine	18 months.
Typhoid Paratyphoid A & B	18 months.
Typhoid Paratyphoid A, B & C.	18 months.
Typhoid Paratyphoid A, B & C and Tetanus Vaccine	18 months.
Typhus Vaccine	12 months.
Yellow Fever Vaccine	12 months.
Viper Venom in Solution	3 months.
Whole Human Blood	2 weeks.

ANTITOXIN

(For salt extracted preparation)

20% excess potency 12 months
30% excess potency 24 months
40% excess potency 36 months
50% excess potency 48 months

(For enzyme digested preparation)

5% excess potency 12 months.
10% excess potency 24 months.
15% excess potency 36 months.
20% excess potency 48 months.

*SCHEDULE Q

(See rules 134 and 144)

List of Coal Tar Colours permitted to be used in Cosmetics

Common name of the Colour	Colour Index Number	Chemical name of the colour
1		3
Guinea Green B	42085	Monosodium salt of 4-(N-ethyl p-sulfo en-zylamino)-diphenylmethylol (I-N- ethyl N-p-sulfonium benzyl) Δ 2,5-cyclohexadi-enimine).

*Added under Government of India Notification No. F. 1-36/C4D dated 15th April, 1964.

THE DRUGS AND COSMETICS RULES

SCHEDULE Q—contd.

1	2	3
Light Green SF Yellowish	42095	Disodium salt of 4-[4 (N-ethyl-p-sulfo benzylamino)-phenyl]-4-sulphoniumphenyl) methylene]-(2 (N-ethyl-N-sulfo benzyl) Δ 2,5-cyclohexadienimine).
Tartrazine	19140	Trisodium salt of 3-carboxy-5-hydroxy-1-p-sulphophenyl-4-p-sulphophenyl azo-pyrazole.
Sunset yellow FCF	15985	Disodium salt of 1-p-sulphophenylazo-2-naphthol-6-sulfonic acid.
Ponceau 3R	16155	Disodium salts of a mixture of 1-alkyl-phenylazo-2-naphthol-3, 6-disulfonic acids.
Amaranth	16185	Trisodium salt of 1-(4-sulfo-1-naphthylazo) 2-naphthol 3, 6-disulfonic acid.
Erythrosine	45430	Disodium salt of 9-O-carboxyphenyl-6-hydroxy 2, 4, 5, 7-tetraiodo-3-isoxanthone.
Ponceau SX	14700	Disodium salt of 2-(5 sulfo-2, 4-xylyl-azo)-1-naphthol-4-sulfonic acid.
Brilliant Blue FCF	42090	Disodium salt of 4-(9-4-(N-ethyl-p-sulfo benzylamino)-phenyl)-2-sulfonium phenyl)-methylene)-(1-(N-ethyl-N-p-sulfo benzyl)- Δ 2, 5-cyclohexadienimine).
Indigocarmine	73015	Disodium salt of 5,5'-indigotindisulfonic acid.
Wool Violet 5 BN(Acid violet 6B)	42640	Monosodium salt of 4-(N-ethyl-p-sulfo benzylamino)-phenyl)-(4-(N-ethyl-p-sulfo benzylamino)-phenyl) methylene)-(N, N-dimethyl- Δ 2,5-cyclohexadienimine).
Light Green SF Yellowish	42095	Calcium salt of 4-(4-(N-ethyl-p-sulfo benzylamino)-phenyl) (4-sulfonium-phenyl)methylene), (1-(N-ethyl-N-p-sulfo benzyl)- Δ 2, 5-cyclohexadienimine)
Alizarin Cyanine Green F	61570	Disodium salt of 1,4-bis(O-sulfo-p-tolueno) anthraquinone.)
Quinazarine Green SS	61565	1,4-bis-(p-Tolueno)-anthraquinene.
Fast Green FCF	42053	Disodium salt of 4-(4-(N-ethyl-p-sulfo benzylamino)-phenyl) (4-hydroxy-2-sulphophenyl) methylene)-(1-N-ethyl-N-p-sulfo benzyl) Δ 2,5, cyclohexadienimine).
Acid Fast Green	42100	Monosodium salt of 4-(4-N-ethyl-p-sulfo benzylamino) phenyl)-(o-chlorophenyl)-methylene)-1-(N-ethyl-N-p-sulfo benzyl- Δ 2, 5, cyclohexadienimine).
Pyranine Concentrated	59040	Trisodium salt of 10-hydroxy-, 3,5,8-pyrene-trisulfonic acid.
Quinoline Yellow WS	47005	Disodium salt of disulfonic acid of 2-(2-Quinoly)-1, 3-indandione.
Quinoline Yellow SS	47000	2-(2-quinoly)-1, 3 indandione.
Ponceau 2 R	16150	Disodium salt of 1 xylylazo-2-naphthol-3, 6-disulfonic acid.
Lithol Rubin B	15850	Monosodium salt of 4-(o-sulfo-p-tolylazo) 3-hydroxy-2-naphthoic acid.
Lithol Rubin BCA	15850	Calcium salt of 4-(o-sulfo-p-tolylazo-3 hydroxy-2-naphthoic acid.

SCHEDULE Q—*contd.*

1	2	3
Lake Red D	15500	Monosodium salt of 1-o-carboxyphenylazo-2-naphthol.
Lake Red DBA	15500	Barium salt of 1-o-carboxyphenylazo-2-naphthol.
Lake Red DCA	15500	Calcium salt of 1-o-carboxyphenylazo-2-naphthol.
Toney Red	26100	1-p-phenylazophenylazo-2-naphthol.
Oil Red OS	26125	1-Xylylazoxylylazo-2-naphthol.
Tetrabromofluorescein	45380	2, 4, 5, 7-Tetrabromo-3, 6-fluorandiol.
Eosin TS	45380	Disodium salt of 2,4,5,7-tetrabromo-9-0 carboxyphenyl-6-hydroxy-3-isoxanthone.
Eosin YSK	45380	Dipotassium salt of 2,4,5,7-tetrabromo-9-0 carboxyphenyl-6-hydroxy-3-isoxanthone.
Tetrachlorofluorescein NA	45366	2,4,5,7 tetrachloro-S, 6-Fluorandiol.
Tetrachlorofluorescein K	45366	Disodium salt of 9-0-carboxyphenyl-2,4, 5,7-tetrachloro-6-hydroxy-3-isoxanthone.
Tetrachloro Tetrabromofluorescein.	45410	2,4,5,7-Tetrabromo-12, 13, 14, 15-tetrachloro-3, 6-fluorandiol.
Phloxine B	45410	Disodium salt of 2,4,5,7-tetrabromo-9 (3,4,5,6-tetrachloro-o-carboxyphenyl)-6-hydroxy-3-isoxanthone.
Bluish Orange T.R. . . .	45457	1,4,5,8, 15-Pentabromo-2, 7-dicarboxy-3, 6-fluorandiol.
Helindone Pink CN	73360	5, 5-Dichloro-3,3' dimethyl-thioindigo
Brilliant Lake Red R. . . .	15800	Calcium salt of 3-hydroxy-4-phenylazo-2-naphthoic acid.
Deep Maroon (Fanchon Maroon)	15880	Calcium salt of 4-(1-sulfo-2-naphthylazo)-3-hydroxy-2-naphthoic acid.
Toluidine Red	12120	1-(o-Nitro-p-tolylazo)-2-naphthol.
Flaming Red	12085	1-(o-Chloro-p-nitrophenylazo)-2-naphthol.
Deep Red (Maroon)	12350	3-Hydroxy-N-(m-nitrophenyl)-4-(o-nitro-p-tolylazo)-2-naphthamide.
Alba Red	13058	o-(p B,B-Dihydroxy-diethylamino)-phenylazo)-benzoic acid.
Orange G	16230	Disodium salt of 1-phenylazo-2-naphthol-6-8-disulfonic acid.
Orange II	15510	Monosodium salt of 1-p-sulfophenylazo-2-naphthol.
Dichlorofluorescein	45365	4,5-Dichloro-3, 6-fluorandiol.
Dichlorofluorescein NA	45365	Disodium salt of 9-0-carboxyphenyl-4,5-dichloro-6-hydroxy-3-isoxanthone.
Diiodofluorescein	45425	4, 5-Diiodo-3, 6-fluorandiol.
Erythrosine Yellowish NA	45425	Disodium salt of 9-0-carboxyphenyl-6-hydroxy-4, 5-diiodo-3-isoxanthone.
Erythrosine Yellowish K	45425	Dipotassium salt of 9-0-carboxyphenyl-6-hydroxy-4, 5, diiodo-3-isoxanthone.
Erythrosine Yellowish NH	45425	Dipotassium salt of 9-0-carboxyphenyl-6-hydroxy 4, 5, diiodo-3-isoxanthone.
Orange TR	45456	4, 5, 15-Tribromo 2, 7-dicarboxy-3, 6-fluorandiol.

THE DRUGS AND COSMETICS RULES

SCHEDULE Q—Contd.

1	2	3
Alizarin	58000	1,2-Anthraquinonediol.
Dibromodiiodo fluorescein	45371	4,5-Dibromo-2, 7- diiodo-3, 6-fluorandiol
Resorcin Brown	20170	Monosodium salt of 4-p-sulfophenylazo-2(2) 4, xylylazo)-1, 3-resorcinol.
Alphazurine FG	42090	Diammonium salt of 4-(N-ethyl-p-sulfobenzyl amine-phenyl) 2-sulfoniumphenyl. methylene (-I (Nethyl-N-p-sulfobenzyl Δ (2, 5-cyclohexadienimine .)
Allarin Astro B	1530	Monosodium salt of 1-methylamino-4-(o-sulfo- p-toluino)-anthroquinone.
Indigo	73000	Indigotin.
Patent Blue NA	42052	Monosodium salt of 4-(4- (N-ethyl-benzyl amino)-phenyl -5 hydroxy-4-sulfo-2-sul- foniumphenyl, methylene) (N-ethyl- Benzyl Δ 2, 5-cyclohexadienimine.
Patent Blue CA	42052	Calcium salt of 4-(4-(N-ethylbenzyl-amino) phenyl - (5-hydroxy-4-sulfo 2 sulfonium- phenyl -methylene, -(N-ethyl-N-benzyl- Δ 2 5-cyclohexadienimine).
Curbranthereine Blue	69825	3, 3- Dichlorolindanthrene,
Nibhihol Blue Black	20470	Disodium Salt of 8-amino-7-p-nitropheny- l zo 3-phenylazo-1-naphthol-3, 6-disulfonic acid.
Alizurol purple SS	60725	I-hydroxy-4-p-tolhuno-anthraquinone.
Acid Red 89	23910	—
Acid Red 97	22890	—
Acid Blue 1	42045	—
Food Blue 3	42045	—
Natural Orange 6	75480	—
Solvent Blues 4	44045	—
Solvent Yellow 18	12740	—
Food Yellow 12	12740	—
Solvent Red 1	12150	—
Solvent Yellow 32	48045	—
Fanchon Yellow (Hansa Yellow G) 11680	(a)	(0-Nitro-p-tolylazo) acetoacetanilide.

SCHEDULE R

(Sec Rule 125)

STANDARDS FOR MECHANICAL CONTRACEPTIVES

(A) Standards for Condoms.

Condoms shall comply with the following standards.

1. Definition—Condoms include wasthalbsheaths.

*Added under Govt. of India, Ministry of Health and Family Planning Notification No. 1-2865- D, dated the 8th March, 1966.

2 *Description*.—Condoms consist of cylindrical rubber sheaths with one end open. The open end has a thin ring round it. The closed end may have a receptacle.

3 *Material*.—Condoms shall be manufactured from good quality rubber latex and shall be free from embedded grit and shall be transparent or translucent prior to the application of dressing materials.

The rubber latex and any dressing materials applied to the condoms shall not liberate substances which are known to have toxic or other harmful effects under conditions of use nor shall any dressing materials have a deleterious effect on the condom itself.

4. *Dimensions*.—

Length.—The overall length of a condom including receptacle shall not be less than 200 mm (limits+ 20 mm).

Width.—The width of a condom when laid flat shall be not less than 49 mm (limits+5 mm and —1 mm.)

Wall thickness.—The wall thickness of a condom shall be as follows :—

<i>Type</i>	<i>Thickness</i>
(1) Washable, light	0.08 to 0.12 mm.
(2) Washable, heavy	0.12 to 0.16 mm.
(3) Others	0.04 to 0.07 mm.

Weight : The weight of a condom shall be as follows :—

<i>Type</i>	<i>Weight</i>
(1) Washable, light with length of 180 mm.	2 to 3 grams
(2) Washable, heavy with length of 180 mm. .	3 to 4 grams
(3) Others	1 to 7 grams

The weight shall be determined by weighing not less than ten specimens individually.

5. *Air inflation test*.—Inflate the condom with air to a diameter of 165 mm. The inflated sample shall be examined for the presence of any pinholes, weak spots or other visible defects likely to affect its use. No such defect shall be discernible.

6. *Water leakage test*.—Fill the condom with 300 ml. of water as described in Figure 1 taking precautions to prevent the spilling of water on the outside surface of the condom. Close its open end harmly by holding it between the fingers, and it necessary wipe the outer surface of the condom with either a cloth pad or a blotting paper to remove any water that may have been accidentally spilt on the outer surface of the condom.

Suspend the filled condom with its open end upwards for not less than 3 minutes. No water droplets are observed.

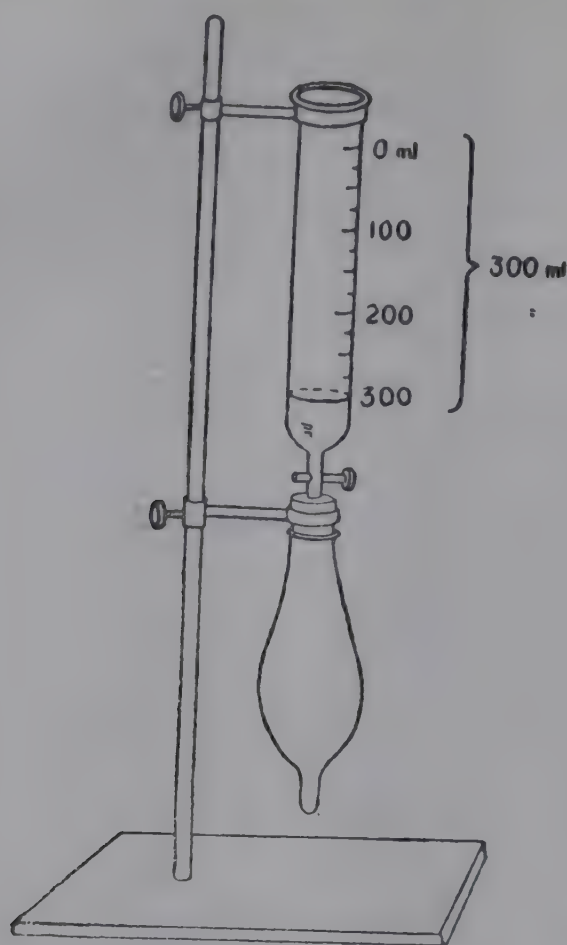


Figure 1

7. Test for tensile strength, elongation at break and tension set—

The average tensile strength, elongation at break and tension set of rubber taken from the samples of condoms shall conform to the following requirements :

Original	After accelerated ageing at $70^{\circ} \pm 1^{\circ}\text{C}$ for 96 hours in air oven Maximum permissible variation.
(i) Tensile strength 140 Kg/Sq. cm	+10 per cent. -15 per cent.
(ii) Elongation at break 650 per cent	± 10 per cent.
(iii) Tension set when the rubber is stretched to 75 per cent of Elongation at break, kept in this stretched condition for 10 minutes and allowed to recover for 10 minutes.	10 per cent maximum.

Rubber specimens for the mechanical tests shall be conditioned at a temperature of $27^{\circ} \pm 2^{\circ}\text{C}$, for a period of 24 hours immediately preceding the tests and tested at the same ambient temperature.

8. Sampling.—The following procedure shall be followed for drawing samples.

Specimens constituting the testing samples shall be taken at random successively from each quantum of production, that is, from the quantity produced from the same finished rubber latex and under the same processing and finishing conditions of manufacture. Samples from each quantum shall be tested separately to ascertain conformity of a quantum with the specified requirements in accordance with the tests described hereinafter.

9. Procedure for testing—

(a) The number of samples drawn from each quantum shall not be less than 1 per cent of the number of condom in each quantum.

(b) The samples drawn from each quantum shall be tested for Air inflation test and Water leakage test in accordance with the methods described under items 5 and 6. Samples subjected to Water leakage test shall be destroyed.

The number of test samples 'N' and the number of rejected samples 'R' from a sequence of production quanta shall be recorded in a register. The cumulative total of test samples 'N' and the cumulative total of rejects 'R' from the test samples shall be recorded and the condoms shall be deemed to comply with the requirements if the cumulative total of rejects 'R' is not more than.

$$0.01N \pm 3\sqrt{0.01N}$$

The following table shows how this formula operates for a typical series of quanta :

TABLE
Sampling of Condoms

Quantum No.	Size of quantum	Number of test samples	Cumulative number tested	Cumulative total of rejects (R) to be not more than
1	10,000	100	100	4
2	5,000	50	150	5
3	5,000	50	200	6
4	10,000	100	300	8
5	20,000	200	500	12

Should the cumulative total of rejects exceed the number of allowable rejects at any point in the sequence of quanta, the quantum at which this occurs shall be liable to rejection. The continued assessment of quality of further production quanta shall include all previous test results starting from quantum Number 1 and approval of production shall be in suspense until the condition required by the scheme is again fulfilled. While approval is in suspense any production quanta giving more than 1.33 per cent defective items shall be rejected; those giving 1.33 per cent defective items or less may be accepted. The results from all these quanta must be included in the series of test results considered before resumption of continuing approval is allowed. However, if a resumption of the overall defective level of not

more than 1 per cent does not occur within a reasonable time, the permission to accept individual quanta giving not more than 1.33 per cent defectives may be withdrawn.

Thirty condoms which have not been subjected to Air inflation test and Water leakage test are used for carrying out the physical tests mentioned above.

10. Labelling and Packing—

(1) The packing shall protect the condoms from contamination and mechanical damage. The smallest packing offered to the consumer shall bear a clear and permanent marking with the following particulars :—

- (i) Manufacturer's name and the trade name of the condom, if any.
- (ii) Batch number.
- (iii) Date of manufacture.
- * (iv) Date of expiry which shall be not more than thirty-six months from the date of manufacture.

(2) The label of the packing shall give a warning against heat, influence of direct sunrays and mechanical damage.

N.B.—*Air Blowers*.—A good manufacturing practice requires that every condom should be subjected to Air inflation test and for this purpose fifteen air blowers are required to be set up to be used for testing purposes.

*SCHEDULES

†SCHEDULE T

[See Rule 157]

Requirements of Factory premises and hygienic conditions.

1. An Ayurvedic (including Siddha) or Unani drug manufacturing Establishment, Pharmacy or Factory shall as far as possible not be situated adjacent to an open sewage, drain, public lavatory or any factory which produces an obnoxious odour or large quantities of soot, dust or smoke. The premises for the manufacture of such drugs shall be clean and hygienic and shall be free from cobwebs, insects, rodents etc.

2. The walls of the room(s) in which manufacturing operations are carried out shall be impervious to water and be capable of being kept clean.

† Added under Govt. of India, Ministry of Health F. P., W. H. and U. D. Notification No. 1-23/67-D, dated 2-2-70.

* Amended by Govt. of India, Ministry of Health, F. P. W.H. & U. D. Notification No. F. 1-32/70-D, dated the 26th May, 1970.

** Deleted under G. S. R. No. 1098 dated 24-7-76. Govt. of India Notification, No. X. 11014/2/76-D&MS dated 9-7-1976.

The flooring shall be smooth and even and shall be such as not to permit retention or accumulation of dust or waste products. The building shall be such as not to give ingress to insects, rodents, reptiles etc.

3. The water used in the manufacture shall be pure and of drinkable quality, free from pathogenic organisms. Adequate provisions of good water for washing the premises shall be made.

4. In factories where operations involving the use of containers such as, bottles, vials, jars etc. are conducted, there shall be adequate arrangements separated from the manufacturing operations for washing, cleaning and drying such containers with suitable equipment for the purpose. Sterilising facilities, where necessary, shall also be provided.

5. Suitable arrangements shall be made for the disposal of waste water and other residues from the manufacturing premises in a manner as may not affect the health of the people in the area.

6. All workers employed in the factory shall be free from contagious or obnoxious disease. The workers shall wear clean white or coloured aprons (to be provided by the management) suitable for the nature of work and climate. Adequate facilities for personal cleanliness such as clean towels, soap and nail scrubbing brushes shall be provided for men and women workers separately. Facilities for drinking water and washing premises shall be provided for each sex separately. Separate provision shall be made for lavatories to be used by men and women, and such lavatories shall be located at places which are well removed from the processing rooms.

*SCHEDULE U

[See Rules 74, 74A, 74-B, 78 and 78-A]

I. PARTICULARS TO BE SHOWN IN MANUFACTURING RECORDS

A. *Substances other than Parenteral preparation in general :*

1. Serial Number.
2. Name of the product.
3. Lot/Batch size.
4. Lot/Batch number.
5. Date of commencement of manufacture and date when manufacture was completed.
6. Name of all ingredients, quantities required for the lot/batch size, quantities actually used. (All weighing and measurements shall be checked and initialled by the competent persons in the Section).
7. Control reference numbers in respect of raw materials used in formulation.
8. Date of mixing in case of dry products e.g. powder, powder mixture for capsule products etc.
9. Date of granulation wherever applicable.

*Added under Govt. of India, Ministry of Health, F.P. and U.D. Notification No. X-20/64-D, dated the 26th October, 1968.

10. Wright of granules.
11. Date of compression in case of tablets/date of filling in case of capsules.
- 11A. Dates of coating wherever applicable.
12. Records of test to be carried out in case of tablets as under :—
 - (a) Average weight every thirty minutes.
 - (b) Disintegration time as often as practicable.
13. Records of readings taken to check weight variation in case of capsules.
14. Reference to Analytical Report number stating whether of standard quality or otherwise.
15. Records on the disposal of rejected batches and batches withdrawn from the market.
16. Actual production and packing particulars indicating the size and quantity of finished packings.
17. Date of release of finished packing for distribution or sale.
18. In case of Hypodermic tablets and ophthalmic preparations which are required to be manufactured under aseptic condition, records shall be maintained indicating the precautions taken during the process of manufacture to ensure that aseptic conditions are maintained.
19. Signature of the Expert staff responsible for the manufacture.

B. Parenteral preparations

1. Serial Number.
2. Name of the product.
3. Lot size.
4. Batch number (if bulk lot is divided into various batches and processed separately, a batch number distinctly different from that of the bulk lot should be assigned to each of the processed batch).
5. Date of commencement of manufacture and date of completion.
6. Name of all ingredients, quantities required for the lot size, quantities actually used. (All weighings and measurements shall be checked and initialled by the competent person in the section).
7. Control reference numbers in respect of raw material used.
8. pH of the solution wherever applicable.
9. Date and methods of filtration.
10. Sterility test reference on bulk batch wherever applicable (if bulk lot is divided into various batches and processed separately, a batch number distinctly different from that of the bulk lot should be assigned to each of the processed batch).

11. Date of filling.
12. Records of tests employed :—
 - (a) To ensure that sealed ampoules are leak-proof.
 - (b) To check the presence of foreign particles.
 - (c) For pyrogens wherever applicable.
13. Records of sterilisation in case of parenteral preparations which are heat sterilised including particulars of time, temperature and pressure employed.
14. Number and size of containers filled and number rejected.
15. Reference to Analytical Report numbers stating whether of standard quality or otherwise.
16. Records of the disposal of rejected batch and batches withdrawn from the market.
17. Actual production and packing particulars.
18. Date of release of finished packings for distribution or sale.
19. Particulars regarding the precautions taken during manufacture to ensure that aseptic conditions are maintained.
20. Control reference numbers in respect of the lot of glass containers used for filling.
21. Signature of the Expert staff responsible for manufacture.

II. RECORDS OF RAW MATERIALS

Records in respect of each raw material shall be maintained indicating the quantity received, control reference numbers, the quantities issued from of which the quantities have been issued and the particulars relating to time to time, the names and batch numbers of the products for the manufacture the proper disposal of the stocks.

III. PARTICULARS TO BE RECORDED IN THE ANALYTICAL RECORDS

A. TABLETS AND CAPSULES.

1. Analytical report number.
2. Name of the sample.
3. Date of receipt of sample
4. Batch/Lot Number.
5. Protocols of tests applied.
 - (a) Description.
 - (b) Identification.
 - (c) Uniformity of weight.
 - (d) Uniformity of diameter (if applicable).
 - (e) Disintegration test (time in minutes).

(f) Any other tests.

(g) Results of assay.

Note.—Records regarding various tests applied (including reading and calculations) should be maintained and necessary reference to these records should be entered in Col. 5 above whenever necessary.

6. Signature of the Analyst.

7. Opinion and signature of the approved Analyst.

B. PARENTERAL PREPARATIONS

1. Analytical report number.

2. Name of the sample.

3. Batch number.

4. Date of receipt of sample.

5. Number of container filled.

6. Number of container received.

7. Protocols of tests applied.

(a) Clarity.

(b) pH wherever applicable.

(c) Identification.

(d) Volume in container.

(e) Sterility—(i) Bulk sample wherever applicable (ii) container sample.

(f) Pyrogen test wherever applicable.

(g) Toxicity test wherever applicable.

(h) Any other tests.

(i) Results of Assay.

Note.—Records regarding various tests applied (including reading and calculations) should be maintained and necessary reference to these records should be entered in Col. 7 above, wherever necessary.

8. Signature of the Analyst.

9. Opinion and signature of the approved Analyst.

Pyrogen Test :

1. Test Report Number.

2. Name of the sample.

3. Batch Number.

4. Number of rabbits used.

5. Weight of each rabbit.

6. Normal temperature of each rabbit.

7. Mean initial temperature of each rabbit.

8. Dose and volume of solution injected into each rabbit and time of injection.
9. Temperature of each rabbit noted at suitable intervals.
10. Maximum temperature.
11. Response.
12. Summed Response.
13. Signature of the Analyst.
14. Opinion and signature of the approved Analyst.

Toxicity Test

1. Test Report Number.
2. Name of the sample.
3. Batch Number.
4. Number of mice used and weight of each mouse.
5. Strength and volume of the drug injected.
6. Date of injection.
7. Results and remarks.
8. Signature of Analyst.
9. Opinion and signature of the approved Analyst.

C. FOR OTHER DRUGS

1. Analytical report number.
2. Name of the sample.
3. Batch/lot number.
4. Date of receipt of sample.
5. Protocols of test applied.
 - (a) Description.
 - (b) Identification.
 - (c) Any other tests.
 - (d) Results of assay.

Note.—Particulars regarding various tests applied (including readings and calculations) shall be maintained and necessary reference to these records shall be entered in Column 5 above, wherever necessary.

6. Signature of the Analyst.
7. Opinion and signature of the approved Analyst.

D. RAW MATERIALS

1. Serial Number.
2. Name of the material.
3. Name of the manufacturer/supplier.
4. Quantity received.

5. Invoice/Challan Number and date.
6. Protocols of tests applied.

Note.—Particulars regarding various tests applied (including readings and calculations) shall be maintained and necessary reference to these records shall be entered in Column 6 above, wherever necessary.

E. CONTAINER, PACKING MATERIAL ETC.

1. Serial Number.
2. Name of the item.
3. Name of the manufacturer/supplier.
4. Quantity received.
5. Invoice/Challan Number and date.
6. Results of tests applied.

Note.—Particulars regarding various tests applied shall be maintained and necessary reference to these records shall be entered in Column 6 above, wherever necessary.

7. Remarks.
8. Signature of the examiner.

Note 1.—The foregoing provisions represent the minimum requirements to be complied with by the licensee. The Licensing Authority, may, however, direct the nature of records to be maintained by the licensee for such products as are not covered by the categories described above.

2. The Licensing Authority may permit the licensee to maintain records in such manner as are considered satisfactory, provided the basic requirements laid down above are complied with.
3. The Licensing Authority may at its discretion direct the licensee to maintain records for such additional particulars as it may consider necessary in the circumstances of a particular case.

***SCHEDULE U (I)**

(See rules 142 and 142-B)

I. Particulars to be shown in the manufacturing Records :

1. Serial number.
2. Name of the product.
3. Lot/Batch size.
4. Lot/Batch number.

*Added by G.S.R. 1594, dated 13-11-1976, Govt. of India Notification No. X. 11014/476-D&MS, dated 28-10-1976.

5. Date of commencement of manufacture and date when manufacture was completed.
6. Names of all ingredients, quantities required for the lot/batch size, quantities actually used.
7. Control reference numbers in respect of raw materials used in formulation.
8. Reference to analytical report number.
9. Actual production and packing particulars indicating the size and quantity of finished packings.
10. Date of release of finished packing for distribution or sale.
11. Signature of the expert staff responsible for the manufacture.

II. Records of Raw Materials :

Records in respect of each raw material shall be maintained indicating the quantity received, control reference number, the quantity issued from time to time, the names and batch numbers of the products for the manufacture of which the said quantity of raw material has been issued and the particulars relating to the proper disposal of the stocks.

NOTE 1 : The Licensing Authority may permit the licensee to maintain records in such manner as is considered satisfactory, provided the basic requirements laid down above are complied with.

NOTE 2 : The Licensing Authority may direct the licensee to maintain records for such additional particulars as it may consider necessary in the circumstances of a particular case.

****SCHEDULE V**

[See rule 124-B]

Standards for patent or proprietary medicines

1. Test for disintegration to be complied with by the manufacturers of patent or proprietary medicines in the form of tablets :

- (i) A patent or proprietary medicine, marketed in the form of a tablet and intended to be swallowed as a whole, when subjected to a test as prescribed in the current edition of the Indian Pharmacopoeia for the time being in force, shall disintegrate in not more than thirty minutes, if it is not coated and in not more than 60 minutes, if it is sugar coated or film coated.
- (ii) In case the tablet referred to in paragraph (i) has an enteric coating or a coating designed to have a similar purpose, it shall not disintegrate when immersed in simulated gastric juice for three hours but shall disintegrate in simulated intestinal juice in another one hour :

Provided that in case any manufacturer wants to manufacture tablets whose disintegration time may be longer than that prescribed above, he shall apply to the Licensing Authority giving sufficient reasons before permission to market such tablets may be granted :

Provided further that the patent or proprietary medicines marketed as sustained release tablets, vaginal tablets or tablets meant to be sucked or chewed or tablets meant for veterinary use, shall not be required to conform to the test for disintegration mentioned above.

***2. Standards for patent or proprietary medicines, containing vitamins :

Patent or proprietary medicines containing vitamins for prophylactic, therapeutic or paediatric use shall contain the vitamins in quantities not less than and not more than those specified below in single or in two divided daily doses, namely :—

**Added under G.S.R. No. 665, dated 28-5-1977 (Govt. of India Notification No. X. 11014/2/77-D & M.S. (100 6-5-1977).

***Added under G.S.R. No. 930, published in the Gazette of India, Pt. II, Sec. 3, Sub-Sec. (i), dated 22-7-1978. (Govt. of India Notification No. X. 11013/2/77-DMS & PFA dated 13th July, 1978.)

Vitamin	Unit	Patent or proprietary medicines containing vitamins for prophylactic use	Patent or proprietary medicines containing vitamins for the therapeutic use	Patent or proprietary medicines containing vitamin for paediatric use	in single dose or in two divided doses.		
					per daily dose		
					For adults	For infants less than one year	For children above one year upto adults
1	2	3	4	5	6		
Vitamin A .	I.U.	Not less than 1600 and not more than 2500.	Not less than 5000 and not more than 10000.	Not less than 750 and not more than 3000.	Not less than 1500 and not more than 5000.		
Vitamin D .	I.U.	Not less than 100 and not more than 200.	Not less than 400 and not more than 1000.	Not less than 200 and not more than 400.	Not less than 100 and not more than 400.		
Vitamin B1 .	mg.	Not less than 1 and not more than 2.	Not less than 4.5 and not more than 10.	Not less than 0.5 and not more than 1.	Not less than 1 and not more than 4.5.		
Vitamin B2 .	mg.	Not less than 1 and not more than 3.	Not less than 5 and not more than 10.	Not less than 0.5 and not more than 1.5.	Not less than 1 and not more than 5.		
Vitamin B6 .	mg.	Not less than 0.5 and not more than 1.5.	Not less than 1.5 and not more than 3.	Not less than 0.5 and not more than 1.5.	Not less than 1 and not more than 3.		
Niacinamide	mg.	Not less than 15 and not more than 26.	Not less than 45 and not more than 100.	Not less than 5 and not more than 15.	Not less than 10 and not more than 40.		
d-Pantothenic acid or its salts and panthenol.	mg.	Not less than 1 and not more than 5.	Not less than 5 and not more than 50.	Not less than 1 and not more than 3.	Not less than 2.5 and not more than 10.		

1	2	3	4	5	6
Folic acid	mcg.	Not less than 50 and not more than 300.	Not less than 1000 and not more than 1500.	Not less than 25 and not more than 100.	Not less than 100 and not more than 500.
Vitamin B12	mcg.	Not less than 0.5 and not more than 1.0.	Not less than 5 and not more than 15.	Not less than 1 and not more than 3.	Not less than 1 and not more than 5.
Vitamin C	mg.	Not less than 25 and not more than 50.	Not less than 75 and not more than 150.	Not less than 20 and not more than 40.	Not less than 30 and not more than 80.
Vitamin E	I.U.	Not less than 5 and not more than 10.	Not less than 15 and not more than 25.	Not less than 2.5 and not more than 10.	Not less than 5 and not more than 20.

Note 1 :

Patent or proprietary medicines containing vitamins intended for prophylactic, therapeutic or paediatric use shall bear on the label the words "For Prophylactic Use" or "For Paediatric Use" as the case may be. In the case of paediatric preparations the age of the infant or the child for whose use it is intended, shall be given in addition to the particulars required to be given under these rules.

Note 2 :

The above standards shall not apply to any preparation containing a single vitamin only and also to any preparation containing vitamins intended for parenteral use.

Provided, however, that in the case of patent or proprietary medicines containing vitamins which are intended for the treatment of certain specific conditions or diseases, the Licensing Authority specified in clause (b) of rule 21, may permit the addition of vitamins therein in relaxation of the limits specified above, if satisfactory evidence is produced in justification of such relaxation.

Notification

No. 1—20/60—D

Government of India

Ministry of Health

New Delhi-2, the 3rd June, 1961

Notification (as periodically amended)

In exercise of the powers conferred by sub-clause (ii) of clause (b) of section 3 of the Drugs Act, 1940 (23 of 1940), the Central Government in supersession of the notifications of the Government of India in the Ministry of Health No. F.1-10/56-D, dated the 20th October, 1956, F. 1-40/59-D, dated the 2nd April, 1960 and No. F. 1-50/59-D, dated the 15th June, 1960, hereby specifies as drugs the following substances namely :—

*1. *Contraceptives.*†2. *Disinfectants*

@(1) Disinfectant fluids made from Coaltar Oils, Coal-tar acids or similar acids derived from petroleum with or without hydrocarbons.

(2) Disinfectant fluids made from synthetic or naturally occurring substances other than those mentioned in (1) above by virtue of their composition possessing disinfectant properties or with claim to possess disinfectant properties.

Sd/- Bashesar Nath
Under Secretary

*Amended by Government of India, Ministry of Health Notification No. F. 1-20/60-D dated the 29-9-1962.

†Amended by Government of India, Ministry of Health and Family Planning Notification No. X. 11013/2/72-D dated the 9th July, 1975.

@Amended by Government of India, Ministry of Health, Family Planning, Works Housing and Urban Development Notification No. F-1-49/68-D., dated the 11th June, 1969.

THE DRUGS AND COSMETICS RULES

*Record of Amendments carried out***Amendment List Number
and date****Amendments carried out****Initials of the person
carrying out
the amendments and
date**

Record of Amendments carried out

Amendment List Number
and date

Amendments carried out

Initials of the
person carrying out
the amendments and
date.

Record of Amendments carried out

Amendment List Number and date	Amendments carried out	Initials of the person carrying out the amendments and date
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Record of Amendments carried out

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and date****Amendments carried out****Initials of the
person carrying out
the amendments and
date**

PDGHS-61

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